Anticipated acquisition by Integra LifeSciences Holdings Corporation of the Codman neurosurgery business

Decision on relevant merger situation and substantial lessening of competition

ME/6682/17

The CMA's decision on reference under section 33(1) of the Enterprise Act 2002 given on 6 July 2017. Full text of the decision published on 3 August 2017.

Please note that [✂] indicates figures or text which has been deleted or replaced in ranges at the request of the parties for reasons of commercial confidentiality or to protect an individual's interest.

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SUMMARY

1. Integra LifeSciences Holdings Corporation (**Integra**) has agreed to acquire the Codman neurosurgery business currently owned by DePuy Synthes (the

Codman business) (the **Merger**). Integra and the Codman business are together referred to as the **Parties**.

2. The Competition and Markets Authority (**CMA**) believes that it is or may be the case that the Parties will cease to be distinct as a result of the Merger, that the share of supply test is met and that, accordingly, arrangements are in progress or in contemplation which, if carried into effect, will result in the creation of a relevant merger situation.

3. The Parties overlap in the UK in the supply of various equipment, instruments and products for use in the performance of neurosurgery, including internal intracranial pressure (**ICP**) monitoring products, external ventricular drain (**EVD**) catheters, EVD collection products, fixed pressure shunts, dural substitutes and cranial access products. The CMA assessed the impact of the Merger on the supply of these products, in each case on a UK-wide basis.

4. The CMA identified competition concerns in relation to the supply of internal ICP monitoring products, standard EVD catheters (or standard and antimicrobial EVD catheters), EVD collection products, and onlay and suturable dural substitutes in the UK. In each case this was on the basis that the Parties had substantial shares of supply, competed closely with each other pre-Merger, and would face limited competition from alternative suppliers post-Merger.

5. The CMA did not identify concerns in relation to the supply of fixed pressure shunts or cranial access products in the UK.

6. The CMA therefore believes that the Merger gives rise to a realistic prospect of a substantial lessening of competition (**SLC**) as a result of horizontal unilateral effects in the UK.

7. However, in this case the CMA has decided to exercise its discretion not to refer the Merger as the markets to which the duty to refer apply are, in aggregate, not of sufficient importance to justify the making of a reference.

8. The Merger will therefore **not be referred** under section 33(1) of the Enterprise Act 2002 (the **Act**).

ASSESSMENT

Parties

9. Integra is a US-based medical technology company that offers solutions in neurosurgery, orthopaedic extremity surgery, plastic surgery, burn care, wound care, reconstructive surgery and general surgery. Its products include

regenerative technology implants, metal implants, instruments and equipment for small bone orthopaedic surgery and specialty surgical applications. The turnover of Integra in 2016 was approximately £734 million worldwide, of which approximately £**[✂]** million was generated in the UK.

10. The Codman business supplies a selection of neurosurgical products and commercialises devices for hydrocephalus management, neuro intensive care and cranial surgery. The Codman business is owned by DePuy Synthes, a wholly owned subsidiary of Johnson & Johnson. The Codman business does not constitute, and has not previously existed as, a separate legal entity. It is comprised of certain assets, including a lease of manufacturing facilities, equipment, intellectual property rights, IT systems, product registrations and permits, business records, goodwill and existing contracts, as well as insurance and cash proceeds. The turnover of the Codman business in 2016 was approximately £**[✂]** million worldwide, of which approximately £**[✂]** million was generated in the UK.

Transaction

11. Integra is proposing to acquire the assets comprising the Codman business from DePuy Synthes by way of an asset purchase agreement, which was executed on 14 February 2017. The Merger was first announced on 15 February 2017. The consideration payable by Integra is approximately USD 1.045 billion.

12. The Parties informed the CMA that the Merger is also the subject of review by competition authorities in India, Spain and the United States.

Jurisdiction

13. As a result of the Merger, the enterprises of Integra and the Codman business will cease to be distinct.

14. As the Parties' have a combined share of supply exceeding 25% with regard to a number of the products in which they overlap, the CMA believes that the share of supply test in section 23 of the Act is met.[1]

15. The CMA therefore believes that it is or may be the case that arrangements are in progress or in contemplation which, if carried into effect, will result in the creation of a relevant merger situation.

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[1] See paragraphs 72, 87, 88, 100, 113, 125, 134 below.

16. The initial period for consideration of the Merger under section 34ZA(3) of the Act began on 30 May 2017 and the statutory 40 working day deadline for a decision is therefore 24 July 2017.

Counterfactual

17. The CMA assesses a merger's impact relative to the situation that would prevail absent the merger (ie the counterfactual). For anticipated mergers, the CMA generally adopts the prevailing conditions of competition as the counterfactual against which to assess the impact of the merger. However, the CMA will assess the merger against an alternative counterfactual where, based on the evidence available to it, it believes that, in the absence of the merger, the prospect of these conditions continuing is not realistic, or there is a realistic prospect of a counterfactual that is more competitive than these conditions.[2]

18. The Parties submitted that **[✂]**. However, **[✂]** the CMA believes the prevailing conditions of competition to be the relevant counterfactual.

Frame of reference

19. Market definition provides a framework for assessing the competitive effects of a merger and involves an element of judgement. The boundaries of the market do not determine the outcome of the analysis of the competitive effects of the merger, as it is recognised that there can be constraints on merging parties from outside the relevant market, segmentation within the relevant market, or other ways in which some constraints are more important than others. The CMA will take these factors into account in its competitive assessment.[3]

Background

20. The Parties overlap in the supply of various surgical equipment, instruments and products for use in the performance of neurosurgery. The Parties' brands are listed in the following table.

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[2] *Merger Assessment Guidelines* (OFT1254/CC2), September 2010, from paragraph 4.3.5. The *Merger Assessment Guidelines* have been adopted by the CMA (see *Mergers: Guidance on the CMA's jurisdiction and procedure* (CMA2), January 2014, Annex D).
[3] *Merger Assessment Guidelines*, paragraph 5.2.2.

Product	Integra brands	The Codman business brands
Internal ICP monitoring systems	Camino	ICP Express, DirectLink, MicroSensor
EVD catheters	Hermetic, TraumaCath	BactiSeal
EVD collections systems	Hermetic Plus, AccuDrain, LimiTorr (not in the UK), MoniTorr ICP (not in the UK)	EDS 3
Fixed pressure shunts	Integra DP, Pudenz, Novus, Ultra, Contour-File, Mishler Dual Chamber Valve	Hakim, Uni-Shunt
Dural substitutes	DuraGen	DuraForm
Cranial access products[4]	N/A	N/A

21. The customers of the Parties in the UK are NHS trusts (accounting for **[✂]**% of the Parties' sales) and some private hospitals. There are 37 primary NHS neurosurgery units in the UK.

22. The Parties submitted that surgeon preference strongly influences which products a hospital decides to procure and whether to switch from one product to another. Such decisions are also subject to scrutiny by procurement teams within hospitals. The CMA spoke with various neurosurgeons and hospitals as part of its market testing, which confirmed this. Neurosurgeons told the CMA that the decision is driven by surgeon familiarity with products and a desire to achieve the best outcomes for patients, although cost is also a factor. It is common for hospitals to multi-source neurosurgical equipment from different suppliers, both to accommodate the individual preferences of different neurosurgeons within a neurosurgery unit and to ensure equipment is available for different needs.

Product scope

23. The Parties overlap in the following products:

    (a) ICP monitoring systems: used to monitor ICP levels. Can be internal or external.

    (b) EVD catheters: used to monitor ICP and to drain excess cerebral spinal fluid (**CSF**).

[4] The Parties do not manufacture their own cranial access products, but rather supply other manufacturers' products.

(c) EVD collection systems: used with EVD catheters to monitor ICP and to drain excess CSF. These consist of a plastic bag, burette, three way valves and tubing, all of which are moulded or extruded plastic products. EVD collection systems are used outside the body.

(d) Shunts: used to treat hydrocephalus which occurs when the brain is unable to re-absorb CSF. A shunt commonly consists of two shunt catheters, a one-way valve, connectors and, sometimes, an associated reservoir. The valve is the central part of the shunt. It regulates the amount, flow, direction and pressure of CSF. When the pressure of CSF inside the brain exceeds a certain threshold, the valve opens and excess CSF drains through the catheter to the downstream cavity.

(e) Dural substitutes: used to close gaps in the dura following surgery.

(f) Cranial access products: used to perform various neurosurgical tasks, including incision and retraction of the scalp, creation of a hole in the cranium to allow devices to be inserted and closing the wound and skin.

24. For each of the products identified above, the CMA first assessed what the appropriate product and geographic frame of reference would be, starting with the narrowest frame of reference in which the Parties overlap. These are discussed in turn below.

ICP monitoring products

25. There are two main methods used by neurosurgeons to monitor ICP levels:[5]

(a) Internal ICP monitoring measures ICP directly in the brain tissue. A transducer is inserted into the cranium via an incision which passes directly into the brain tissue. The Parties told the CMA that this method has a lower complication rate, but is significantly more expensive than external ICP monitoring.

(b) External ICP monitoring involves adding an external transducer and an EVD collection system to the EVD catheter allowing ICP measurements as well as drainage of CSF. The Parties told the CMA that this method

[5] The Parties submitted that they both have “ventricular” ICP sensors (eg Integra’s Camino Flex Ventricular Catheter) that are intended for both the monitoring of ICP and the drainage of CSF. However, the use of these types of ICP sensor is not a preferred technique in Europe as they are associated with a perceived high risk of infections. The preferred approach in Europe is to use ICP sensors for monitoring and to have a second ventricular EVD catheter in the ventricle connected to an EVD collection bag to allow for drainage of CSF. For this reason, Integra’s Camino Flex Ventricular Catheter is not sold in the UK.

has a greater risk of infection and a greater risk that the catheter may become blocked as it is draining CSF at the same time, but costs less.[6]

26. The Parties overlap in the supply of internal ICP monitoring products. Neither of the Parties supply external ICP monitoring products.

27. The Parties submitted that, in most cases, internal and external ICP monitoring could be considered substitutes from a clinical perspective, with the choice between internal or external ICP monitoring driven by practitioners' preferences as well as clinical advantages and disadvantages. All competitors that responded to the CMA's market investigation told the CMA that internal and external ICP monitoring essentially perform the same function. However, two surgeons told the CMA that external ICP monitoring is not commonly performed in the UK and is more appropriate for the drainage of excess CSF than for monitoring ICP.

28. From the supply side, there was limited evidence that production assets for external ICP monitoring products could be easily used to produce internal ICP monitoring products. There are also differences between the competitor set for internal ICP monitoring and external ICP monitoring.

29. On the basis of the evidence set out above, and on a cautious basis, the CMA has assessed the effect of the Merger on the narrowest plausible frame of reference in which the Parties overlap, which is the supply of internal ICP monitoring products.

EVD catheters

30. EVD catheters can be either standard or antimicrobial. The Parties told the CMA that the main advantage of antimicrobial EVD catheters is that they reduce the risk of infections.[7] The Parties estimate that standard EVD catheters are still being used more often than antimicrobial and represent around [60-70]% of all EVD catheters used in the UK by volume.

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[6] In addition, there are other non-invasive technologies to measure ICP that do not involve inserting sensors into the skull. These include ultrasound, near-infrared spectroscopy and optic nerve sheath diameter. The CMA understands that these technologies are only emerging and have not yet built a sizeable customer base. Given surgeon's preferences for equipment with which they have trained and are familiar, the CMA does not believe that these technologies will become a significant alternative to internal or external ICP monitoring in the near future.

[7] Antimicrobial EVD catheters can be further divided into silver-lined and antibiotic-treated. Some third parties noted that there is an ongoing study of standard, silver-lined and antibiotic-impregnated EVD catheters which is seeking to establish which type of EVD catheter provides the most protection against infection and to ensure standardisation of care and infection rates across the UK. Neurosurgeons told the CMA that the findings of this study, due to be concluded in 2018, could be influential to the future demand for different types of EVD catheters in the UK.

31. The Parties overlap in the supply of standard EVD catheters. The Codman business also supplies antimicrobial EVD catheters but Integra does not. **[✂]**.[8]

32. The Parties submitted that hospitals and physicians are increasingly using antimicrobial EVD catheters. Third parties confirmed this trend:

(a) All neurosurgeons who were asked about antimicrobial EVD catheters agreed that the market was moving towards an increased use of these products over standard EVD catheters. One surgeon told the CMA that antimicrobial EVD catheters are becoming the standard. Another surgeon said that new antimicrobial EVD catheters are coming into the market, but some hospitals may still use standard EVD catheters for a variety of reasons (eg because the clinical case for antimicrobial EVD catheters has not been made at that particular hospital).

(b) All competitors that responded to the CMA's questionnaire submitted that standard and antimicrobial EVD catheters perform the same function and therefore can be seen as alternatives. For example, a competitor submitted that an antimicrobial coating is an ancillary feature. Another competitor submitted that antimicrobial and standard EVD catheters are close alternatives as they perform the same function, though standard EVD catheters are not acceptable in some hospitals due to the higher infection risk.

(c) One hospital customer told the CMA that, although functionally they are similar products, different hospitals, and indeed different neurosurgeons, will have different preferences between antimicrobial and standard EVD catheters. One neurosurgeon told the CMA the clinical evidence for the relative benefits of antimicrobial EVD catheters is not strong, but he also acknowledged that some colleagues may disagree.

(d) An internal document of Integra states that **[✂]**.[9]

33. From the supply side, while standard EVD catheters are supplied by those producers which supply antimicrobial EVD catheters, only the Codman business, Spiegelberg and Medtronic currently produce antimicrobial EVD catheters.[10] The Codman business previously had a patent for its antibiotic impregnated EVD catheters, which recently expired.

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[8] **[✂]**.
[9] The CMA notes that **[✂]**.
[10] While Medtronic produces an antimicrobial EVD catheter it does not currently supply this into the UK.

34. The CMA has not received compelling evidence that the assets used to supply standard EVD catheters could be readily used to supply antimicrobial EVD catheters, although it may be possible to adapt the assets producing antimicrobial EVD catheters to produce standard EVD catheters.

35. The CMA understands that there may be challenges for a firm seeking to develop an antimicrobial EVD catheter, which may not be faced by a firm seeking to enter the supply of standard EVD catheters, including the significant greater investment needed to develop the technology. Conversely, there are doubts over whether a firm producing only antimicrobial EVD catheters would have the incentives to expand into producing standard EVD catheters when doing so may move customers away from the higher margin product.

36. Given the mixed evidence on both demand and supply side substitutability between standard and antimicrobial EVD catheters, and uncertainty as to the future demand for these products, the CMA assessed the effect of the Merger on alternative frames of reference for (i) the supply of standard EVD catheters, and (ii) the supply of both standard and antimicrobial EVD catheters.

EVD collection systems

37. The Parties submitted that, while EVD collection systems are technically simple products, there are differentiating features which influence practitioner preferences. The most significant differentiating feature is whether the system is standard or automated:

    (a) Standard systems rely on excess CSF being collected by using a combination of gravity and intracerebral pressure, while the patient remains stationary.

    (b) Automated systems have a mechanism which prevents the over-drainage of CSF, enabling patients to move around without affecting the system. The Parties submitted that this system is particularly suitable for patients undergoing shunt investigations.

38. The Parties overlap in the supply of standard EVD collection systems. Neither of the Parties supply automated EVD collection systems. The CMA understands that there are very few automated EVD collection systems supplied in the UK, with Moller Medical the only supplier.

39. The Parties submitted that collection systems are used in all areas of a hospital and, while bags are customised for EVD collection, they do not differ significantly in technology or production from bags used elsewhere in a

hospital. However, the CMA found that different firms compete to supply these products and the conditions for competition between firms are unlikely to be the same for different collection systems. The CMA did not receive compelling evidence from the Parties or competitors that the assets used to produce collection systems for other needs in hospitals could be utilised to quickly and easily supply EVD collection systems. Third parties suggested that branding, reputation and clinicians' experience of using different products create barriers to entry for suppliers not currently active in the supply of EVD collection systems.

40. On the basis of the evidence set out above, the CMA has assessed the effect of the Merger in the supply of EVD collection systems.

Shunts

41. There are three different types of shunt, depending on the valve:[11]

(a) Fixed pressure shunts have a predetermined fixed setting (opening pressure) that cannot be changed without surgical intervention.

(b) Flow regulating shunts allow for a continuous flow of CSF at a fixed rate (unlike fixed and programable shunts). The flow mechanism automatically adjusts to the patient's needs to maintain a physiological flow rate. Changing the set range requires surgical intervention.

(c) Programmable shunts have a valve that opens when a pressure threshold is exceeded. Settings can be adjusted without surgical intervention.[12]

42. Integra supplies fixed pressure and flow regulating shunts, while the Codman business supplies fixed pressure and programmable shunts. Therefore, the principal overlap between the Parties is in fixed pressure shunts, while an alternative overlap might be considered across all shunts (including fixed, flow-regulating, and programmable).

43. The Parties submitted that, while all types of shunt are used to treat hydrocephalus and to drain excess CSF from the brain and are therefore broadly substitutable, on a conservative basis the relevant product frame of reference is fixed pressure shunts.

44. The CMA considered evidence of demand side substitution between the different shunts. The Parties submitted that fixed pressure shunts are less

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[11] Valves are typically supplied as a single unit, but can also be supplied in a pack with EVD catheters.

[12] Shunts can also be supplied with either antimicrobial catheters or with standard catheters. Typically, suppliers which have developed antimicrobial catheters can (and do) supply shunts in antimicrobial and standard form.

technologically advanced than other types of shunts and that the market for fixed pressure shunts is declining as demand shifts towards programmable shunts. However, evidence from third parties suggests that fixed pressure shunts remain popular, and programmable or flow-regulating shunts are more likely to be used to meet specific patient needs:

(a) One surgeon told the CMA that he primarily uses fixed pressure shunts and only uses other shunts if fixed pressure shunts are not working well for that particular patient or for complex cases (in total around 10% of cases). The surgeon also said that there is no need to adjust fixed pressure shunts once they are implanted and they are therefore the best option, particularly given their lower price.

(b) Two other third parties submitted that programmable valves might be more suitable for use in paediatrics to enable post-operative "fine tuning" and to avoid further operations as children's bodies grow. A customer said that, in some situations, programmable shunts are more suitable, eg for elderly or young patients.

(c) One neurosurgeon submitted that the only neurosurgeons who use a flow-regulating shunt are those who were trained by a certain neurosurgeon in Paris. For this reason, he did not consider these shunts to be in the same product market as fixed pressure shunts.

45. The CMA understands that there are significant price differences between the different shunt types, with fixed pressure shunts being significantly cheaper than programmable shunts (around 3 times cheaper) and flow regulating shunts (around 2 times cheaper).

46. From the supply side, the technology to produce programmable and flow regulating shunts is different to that required for fixed pressure shunts. The Parties told the CMA that the equipment used by Integra to produce fixed pressure shunts is based on technology dating back to the 1950s, while both Parties have patented their respective flow regulating and programmable valves, indicating limited opportunity for supply side substitution.

47. On the basis of the evidence set out above, the CMA has assessed the effect of the Merger in the supply of fixed pressure shunts only. However, the CMA notes that, even if a broader frame of reference were used, incorporating all shunts, this would not affect the CMA's conclusions as flow-regulating shunts comprise a small share of this wider market and the increment from the Merger would still be small (as further discussed below).

Dural substitutes

48. The dura is the protective membrane surrounding the brain and spinal cord. Where the dura is resected (ie cut out) as a result of cranial surgery or damaged as a result of injury or disease, it may need to be repaired to ensure watertight closure and to avoid leakage of CSF. There are multiple means of closing gaps in the dura: direct suturing, suturing with a sealant,[13] or using a graft – either from a patient's own body (an autograft), from another human (an allograft), from another species (a xenograft), or from a synthetic source.

49. The CMA understands that autografts and allografts are not commercially supplied products (ie the tissue is taken directly from the patient or another person), and therefore it has not considered these products further.

50. The Parties submitted that xenografts and synthetic grafts are used most often for dura repair and are supplied in onlay and suturable form:

    (a) Onlay grafts are used where the location of the graft does not require suturing of the dural substitute. Such grafts have the benefit of being relatively easy to use, needing only be laid on to the opening.

    (b) Suturable grafts have greater tensile strength to enable suturing. They can be used in all locations and are particularly suitable for surgeries on the side or bottom of the skull.

51. Integra manufactures and supplies dural substitutes in onlay and suturable forms, while the Codman business supplies dural substitutes in an onlay form only, which it sources from a third party.

52. The Parties submitted that some grafts (such as those produced by Medtronic, Stryker and B. Braun) are specifically marketed as "versatile" grafts, which can be used either as an onlay or sutured. Medtronic confirmed that its product can be used either as an onlay or suturable graft.

53. The Parties submitted that the method employed to close the dura primarily depends on surgeon preferences, as well as on whether direct suturing is an option (eg depending on where on the skull or spine the dura needs to be repaired). A hospital and most surgeons with whom the CMA spoke confirmed this. For example, one surgeon said that there is no guidance on whether surgeons should use a suturable or onlay graft and that each surgeon has a different view. Another surgeon told the CMA that onlay and suturable grafts

[13] Dura sealants are used as a complementary product to dural substitutes. Integra supplies a dural repair sealant, but the Codman business does not.

can be used interchangeably and surgeons will make the decision on whether to use an onlay or suturable graft based on the specific needs of a patient.

54. One competitor submitted that suturable and onlay grafts are close alternatives, while another submitted that they are close but have different applications (ie a suturable graft is used when the pressure and leak rate is higher). Another competitor submitted that onlay and suturable onlay grafts are close alternatives but onlay and suturable only grafts are not close alternatives as there are different indications for these products, though he acknowledged that there is still some overlap depending on clinical preference.

55. On the supply side, the CMA notes that most suppliers either produce a dura substitute which is versatile (ie can be used as onlay or sutured) and/or produce both types of dura substitutes (ie onlay and suturable). This suggests there could be some degree of supply side substitution.

56. On the basis of the evidence set out above, the CMA has assessed the effect of the Merger using a frame of reference encompassing both onlay and suturable dural substitutes. The CMA has taken into account the differentiation between these dural substitutes in its competitive assessment. The CMA notes that, even if a narrower frame of reference was used, this would not affect the CMA's conclusions.

Cranial access products

57. The Parties submitted that cranial access products are basic commodities supplied by a large number of firms. These products include razors, syringes, needles, drapes, sponges, gauzes, swabs, ointments, hand drills, scalpels, forceps and scissors.

58. The Parties do not produce these products but source them from third party manufacturers.

59. The Parties submitted that the vast majority of cranial access products in the UK are sold on a standalone basis, although a small number of products are sold together in a bundled form (as a "kit"). However, the CMA has not considered each of the products within the cranial access kit as a separate frame of reference as most of these products are not neurosurgery specific (eg scissors or razors).

60. The CMA notes that these products are not particularly specialised or differentiated. In particular, intellectual property, innovation, and quality do not appear to be significant differentiators.

61. The CMA assessed the effect of the Merger considering all the cranial access products for which the Parties overlap. However, as the CMA did not find competition concerns on any plausible basis with regard to these products, it was not necessary for the CMA to conclude on the appropriate product frame of reference.

Conclusion on product scope

62. For the reasons set out above, the CMA assessed the impact of the Merger in each of the following product frames of reference: internal ICP monitoring products, standard EVD catheters (and standard and antimicrobial EVD catheters), EVD collection systems, fixed pressure shunts, onlay and suturable dural substitutes and cranial access products.

Geographic scope

63. The Parties submitted that the geographic frame of reference is broader than national because the relevant products are supplied unmodified internationally, with no national regulatory restrictions in the UK that prevent firms from manufacturing products outside the UK for supply into the UK. They also submitted that there are no regulatory barriers to selling medical devices across the EEA as the products have to meet a common standard before being sold in any EU market.[14]

64. Nevertheless, the Parties acknowledged that prices differ significantly across the EEA. In addition, an internal document of Integra shows **[✂]**. This indicates different competitive conditions across EEA countries.

65. Third parties also told the CMA that having a sales team or a distributer based in the UK is an important factor to compete effectively in the UK.

66. On the basis of this evidence, the CMA assessed the impact of the Merger on a UK-wide basis for each product frame of reference listed above.

Conclusion on frame of reference

67. For the reasons set out above, the CMA assessed the impact of the Merger on the supply of:

    - internal ICP monitoring products;

[14] A CE mark is a mandatory conformity marking accredited to certified products in the EEA.

- standard EVD catheters (and standard and antimicrobial EVD catheters);
- EVD collection systems;
- fixed pressure shunts;
- onlay and suturable dural substitutes; and
- cranial access products,

in each case on a UK-wide basis.

Competitive assessment

Horizontal unilateral effects

68. Horizontal unilateral effects may arise when one firm merges with a competitor that previously provided a competitive constraint, allowing the merged firm profitably to raise prices or to degrade quality on its own and without needing to coordinate with its rivals.[15] Horizontal unilateral effects are more likely when the merging parties are close competitors.

69. The CMA assessed whether it is or may be the case that the Merger has resulted, or may be expected to result, in an SLC in relation to horizontal unilateral effects in each of the frames of reference identified above.

Internal ICP monitoring products

The Parties' views

70. The Parties submitted that they have different product offerings that are not the closest substitutes to each other, and they are constrained by a number of significant competitors, in particular Raumedic. The Parties said that Raumedic is now the most technologically advanced supplier of internal ICP monitoring products and is competing aggressively.

Shares of supply

71. The Parties provided the following shares of supply by value in the UK for the past five years, noting that the shares for competitors are the Parties' best estimates. The CMA was not able to verify all shares with third parties; in particular, prior to 2016. However, based on the Parties' calculation

[15] *Merger Assessment Guidelines*, from paragraph 5.4.1.

methodology and information provided by third parties, the CMA believes these estimates to be reasonable.

Internal ICP monitoring, UK					
	Value, £				
	2012	**2013**	**2014**	**2015**	**2016**
Total demand	[2-3] million	[2-3] million	[2-3] million	[2-3] million	[2-3] million
Integra	[10-20]%	[10-20]%	[20-30]%	[20-30]%	[10-20]%
The Codman business	[60-70]%	[60-70]%	[50-60]%	[50-60]%	[40-50]%
Combined	*[80-90]%*	*[80-90]%*	*[80-90]%*	*[70-80]%*	*[60-70]%*
Raumedic	[0-5]%	[0-5]%	[0-5]%	[10-20]%	[10-20]%
Spiegelberg	[10-20]%	[10-20]%	[10-20]%	[10-20]%	[10-20]%
Sophysa	[0-5]%	[5-10]%	[5-10]%	[5-10]%	[10-20]%
	Volume, units				
Total demand	[5-10] thousand	[5-10] thousand	[5-10] thousand	[5-10] thousand	[5-10] thousand
The Parties combined	*[80-90]%*	*[80-90]%*	*[80-90]%*	*[70-80]%*	*[60-70]%*
Source: Parties' estimates. Estimates for value include sales of ICP sensors and accessories; for volume estimates include ICP sensors only.					

72. The table shows that the Parties would hold a high combined share of supply post-Merger ([60-70]%). The Parties' estimates indicate that the **[✂]**.

Closeness of competition

73. The above shares indicate that the Codman business and Integra are the largest and second largest suppliers of internal ICP monitoring products in the UK.

74. Most customers and all competitors that responded to the CMA's questions said that they considered the Parties to offer competing products. Competitors noted that the Parties' products shared a similar technology. However, third parties also noted qualitative differences in the Parties' offerings.

75. All five neurosurgeons with whom the CMA spoke expressed the view that the Codman business's ICP monitoring product was the most commonly used across the UK. Two surgeons suggested that Integra's ICP monitoring technology was now a relatively old product.

76. Internal documents provided by the Parties mention **[✂]**. For example, a document of the Codman business[16] **[✂]**[17]. **[✂]**.

77. The CMA also reviewed sales data provided by the Parties, which indicated that a substantial share of customers purchased ICP monitoring products from both of the Parties in the last five years, indicating some substitutability between them.[18]

78. On the basis of this evidence, the CMA believes that the Parties are close competitors in the supply of internal ICP monitoring products.

Competitive constraints

79. Post-Merger, the second largest supplier of internal ICP monitoring products will be Raumedic, with around [10-20]% share of supply. While Raumedic has increased its share in recent years, it would still be significantly smaller than the combined entity in this product area.

80. Some customers identified Raumedic as having the most advanced internal ICP monitoring product, but they also indicated limited appetite to switch due to their familiarity with the Parties' products. Several neurosurgeons confirmed that Raumedic is an alternative to the Parties' products. Few customers identified Spiegelberg or Sophysa as alternatives to the Parties' ICP monitoring products.

81. Of the five competitors that responded to the CMA's questionnaire, two listed Raumedic as a close competitor to the Parties' products. Spiegelberg was also mentioned as an alternative by two out of five competitors, and Sophysa was mentioned by one competitor.

82. An internal document of Integra lists the Codman business, Raumedic and Sophysa as global competitors to Integra in ICP monitoring, while an internal document of the Codman business lists Integra, Raumedic and Sophysa as their global competitors.

83. On the basis of this evidence, the CMA believes that Raumedic will provide some competitive constraint on the Parties post-Merger. Although Spiegelberg and Sophysa are possible suppliers, the evidence suggests that they are not seen by customers currently as strong alternatives in the UK.

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[16] **[✂]**.
[17] **[✂]**.
[18] In the period between 2012 and 2016, out of 37 primary neurosurgery units, **[✂]** units made purchases for ICP monitoring products from both Parties in more than one year.

Conclusion on horizontal unilateral effects in the supply of internal ICP monitoring products

84. For the reasons set out above, the CMA believes that the Parties will have a very large share of supply in internal ICP monitoring post-Merger and they are close, if not the closest, competitors to each other for these products. They will face limited competitive constraints post-Merger, with Raumedic providing the only significant constraint. Accordingly, the CMA believes that the Merger gives rise to significant competition concerns as a result of horizontal unilateral effects in the supply of internal ICP monitoring products in the UK.

EVD catheters

The Parties' views

85. The Parties submitted that:

(a) Integra is a peripheral supplier of EVD catheters in the UK. It does not offer an antimicrobial EVD catheter, so the overlap is limited to standard EVD catheters.

(b) The Parties are not close competitors in EVD catheters. The Codman business is focussed on selling its antimicrobial EVD catheter, for which Spiegelberg, with its silver-lined EVD catheter, is its closest competitor in the UK. Medtronic is the largest supplier of standard EVD catheters and the closest competitor to the Parties for this product.

Shares of supply

86. The Parties provided the following shares of supply by value in the UK for the past five years, noting that the shares for competitors are the Parties' best estimates. The shares are provided on alternative bases, for (i) standard EVD catheters only and (ii) standard and antimicrobial EVD catheters together. The CMA also estimated shares for 2016, using information provided by the Parties and third parties, as presented in the last column in the table.

Standard (non-antimicrobial) EVD catheters, UK						**CMA estimates**
	Value, £					
	2012	**2013**	**2014**	**2015**	**2016**	**2016**
Total demand	[0-1] million	[0-1] million	[0-1] million	[0-1] million	[0-1] million	[0-1] million
Integra	[10-20]%	[10-20]%	[10-20]%	[10-20]%	[10-20]%	[20-30]%
The Codman business	[10-20]%	[10-20]%	[20-30]%	[10-20]%	[10-20]%	[20-30]%

Combined	*[20-30]%*	*[30-40]%*	*[30-40]%*	*[30-40]%*	*[20-30]%*	*[40-50]%*
Spiegelberg	[10-20]%	[10-20]%	[10-20]%	[10-20]%	[10-20]%	[✂]
Medtronic	[50-60]%	[40-50]%	[40-50]%	[40-50]%	[40-50]%	[✂]
Sophysa	[5-10]%	[5-10]%	[5-10]%	5-10]%	[5-10]%	[✂]
Raumedic	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[✂]
	Volume, units					
Total demand	[5-10] thousand	[5-10] thousand	[5-10] thousand	[5-10] thousand	[5-10] thousand	
Combined	*[20-30]%*	*[30-40]%*	*[30-40]%*	*[30-40]%*	*[20-30]%*	
Source: The Parties estimates and third party submissions.						

87. In a narrower frame of reference (ie standard EVD catheters only), the Parties have a combined share of supply between [20-30]% and [50-60]%, with the largest suppliers in this frame of reference post-Merger being the Parties and Medtronic.

All EVD catheters, UK						**CMA estimates**
	Value, £					
	2012	**2013**	**2014**	**2015**	**2016**	**2016**
Total demand	[1-2] million	[1-2] million	[1-2] million	[1-2] million	[1-2] million	[1-2] million
Integra	[0-5]%	[5-10]%	[5-10]%	[5-10]%	[5-10]%	[5-10]%
The Codman business	[40-50]%	[50-60]%	[50-60]%	[50-60]%	[40-50]%	[40-50]%
Combined	*[50-60]%*	*[50-60]%*	*[60-70]%*	*[50-60]%*	*[50-60]%*	*[50-60]%*
Spiegelberg	[20-30]%	[20-30]%	[20-30]%	[20-30]%	[20-30]%	[✂]
Medtronic	[10-20]%	[10-20]%	[10-20]%	[10-20]%	[10-20]%	[✂]
Sophysa	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[✂]
Raumedic	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[✂]
	Volume, units					
Total demand	[10-20] thousand	[10-20] thousand	[10-20] thousand	[10-20] thousand	[10-20] thousand	
Combined	*[40-50]%*	*[40-50]%*	*[40-50]%*	*[40-50]%*	*[40-50]%*	
Source: The Parties' estimates and third party submissions.						

88. In a wider frame of reference (ie including standard and antimicrobial EVD catheters), the Parties have a combined share of supply between [50-60]% and [50-60]%, although the increment is small at [5-10]%.

Closeness of competition and competitive constraints

- *Standard EVD catheters*

89. The Parties submitted that standard EVD catheters are low-cost devices based on simple technologies. This was confirmed by third parties. A competitor told the CMA that there is limited potential for differentiation in standard EVD catheters, so competition mainly occurs on price. This was consistent with evidence from customers of the Parties.

90. The undifferentiated nature of standard EVD catheters is in contrast to antimicrobial EVD catheters, which tend to have a greater degree of differentiation, eg in the technology used (such as Spiegelberg's silver-lined products).

91. Most third parties told the CMA that the Parties are close competitors in the supply of standard EVD catheters, with Medtronic being identified as the primary alternative to the Parties. B. Braun was mentioned by one hospital customer as an alternative while Spiegelberg was mentioned as an alternative by several third parties. Sophysa was mentioned as an alternative by one competitor.

- *Standard and antimicrobial EVD catheters*

92. As set out in the frame of reference section above, the evidence received by the CMA indicates that antimicrobial EVD catheters impose a degree of constraint on standard EVD catheters.

93. Spiegelberg, which produces a silver-lined antimicrobial EVD catheter, was identified by the Parties and third parties as a significant and credible supplier of antimicrobial EVD catheters.

94. In addition to Spiegelberg, the Parties identified Medtronic as a possible supplier of antimicrobial EVD catheters in the UK. The CMA understands that Medtronic currently supplies an antimicrobial EVD catheter into the US but does not do so into the UK. **[✂]**.

95. In the last three years, the Codman business sold approximately **[✂]**. This would suggest that Spiegelberg is a closer competitor to the Codman business for EVD catheters than Integra.

Conclusion on horizontal unilateral effects in the supply of standard EVD catheters and standard and antimicrobial EVD catheters

96. For the reasons set out above, the CMA believes that:

(a) in a frame of reference for the supply of standard EVD catheters in the UK only, the Parties will have a large share of supply post-Merger and are close competitors to each other. They will face limited competitive constraints post-Merger, with Medtronic providing the only significant constraint; and

(b) in a frame of reference for the supply of both standard and antimicrobial EVD catheters, the Parties will have a large share of supply post-Merger, and they are close competitors, albeit with some significant differentiation between them. They will face limited competitive constraints post-Merger, with Spiegelberg and Medtronic providing the only significant constraint.

97. Accordingly, the CMA believes that the Merger gives rise to significant competition concerns as a result of horizontal unilateral effects in the supply of standard EVD catheters (and standard and antimicrobial EVD catheters) in the UK.

EVD collection systems

The Parties' views

98. The Parties submitted that Medtronic is not only the largest supplier of EVD collection systems but is also the closest competitor to each of the Parties. The Parties submitted that, in addition, there are a number of other significant competitors. The Parties also said that a number of potential competitors which are already supplying neurosurgical products could easily expand their offerings to include EVD collection.

Shares of supply

99. The Parties provided the following shares of supply by value in the UK for the past five years, noting that the shares for competitors are the Parties' best estimates. The CMA was not able to verify all shares with third parties, in particular prior to 2016. However, based on the Parties' calculation methodology and information provided by third parties, the CMA believes these estimates to be reasonable.

EVD collection systems, UK					
	Value, £				
	2012	**2013**	**2014**	**2015**	**2016**
Total demand	[1-2] million	[1-2] million	[1-2] million	[1-2] million	[1-2] million
Integra	[10-20]%	[10-20]%	[20-30]%	[20-30]%	[20-30]%
The Codman business	[20-30]%	[30-40]%	[20-30]%	[20-30]%	[10-20]%
Combined	*[30-40]%*	*[40-50]%*	*[50-60]%*	*[40-50]%*	*[40-50]%*

Medtronic	[50-60]%	[40-50]%	[40-50]%	[40-50]%	[50-60]%
Sophysa	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Spiegelberg	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Raumedic	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Moller Medical	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
	Volume, units				
Total demand	[10-20] thousand	[10-20] thousand	[10-20] thousand	[10-20] thousand	[10-20] thousand
Combined	*[30-40]%*	*[40-50]%*	*[40-50]%*	*[40-50]%*	*[40-50]%*

Source: Parties' estimates. Estimates for value include EVD drainage systems and replacement bags; for volume estimates include EVD drainage systems only.

100. The table indicates that the Parties' combined share of supply in EVD collection systems is about [40-50]%.

Closeness of competition and competitive constraints

101. The estimated shares show that Medtronic is the largest supplier of EVD collection systems in the UK. The combined entity and Medtronic would, post-Merger, account for over [90-100]% of the supply of EVD collection systems in the UK. Other suppliers, including Sophysa, Spiegelberg, Raumedic and Moller Medical would together account for less than [0-5]% of supply.

102. The Parties submitted that EVD collection systems are somewhat differentiated, suggesting that the CMA should place less weight on shares of supply. However, third parties told the CMA that there are no major differences in EVD collection systems offered by different suppliers. Two neurosurgeons told the CMA that they are happy for their procurement teams to source the cheapest products.

103. Third parties confirmed that the Parties and Medtronic are the main suppliers of EVD collection systems, with few customers listing Sophysa, Spiegelberg or Raumedic as alternatives. One neurosurgeon explained that, post-Merger, Medtronic and the combined entity would be the only large suppliers.

104. Half of the competitors responding to the CMA listed Medtronic as a main competitor, whereas only a quarter identified Raumedic as a competitor and another quarter highlighted Sophysa or Spiegelberg as credible alternatives. Two out of three hospital customers identified Medtronic as a credible alternative, whilst one hospital noted that B. Braun's product (which was not cited as an alternative by the Parties) was an alternative.

105. Medtronic is the largest supplier of EVD collection systems, as indicated by its share of supply. Medtronic submitted that it offers a similar product and technology to the Parties.

106. One of Integra's internal documents **[✂]**.

107. The CMA considered sales data provided by the Parties. The sales data indicated that the Parties are close competitors given a substantial share of customers purchased EVD collection systems from both of the Parties in the last five years.[19]

108. The Parties submitted that Spiegelberg could leverage its strong position in antimicrobial EVD catheters to win customers in EVD collection. However, the CMA notes that Spiegelberg has a very small share in EVD collection, and third parties told the CMA that EVD catheters are usually purchased separately from EVD collection systems.

109. The Parties also submitted that Moller Medical offers an automated CSF drainage function, with which it could expand its presence in the UK. The system is suitable for all patients but could be a preferred option for patients who are mobile. The Parties submitted that the system is currently being marketed in the UK and has been sold to a number of UK customers. However, the CMA notes that Moller Medical has made relatively few sales in the UK of this product and it is unclear whether Moller Medical will gain share at the expense of the Parties. For this reason, the CMA believes that Moller Medical exercises a limited constraint on the Parties.

Conclusion on horizontal unilateral effects in the supply of EVD collection systems

110. For the reasons set out above, the CMA believes that the Parties will have a large share of supply in EVD collection systems post-Merger and are close competitors to each other. They will face limited competitive constraints post-Merger, with Medtronic providing the only significant constraint. Accordingly, the CMA believes that the Merger gives rise to significant competition concerns as a result of horizontal unilateral effects in the supply of EVD collection systems in the UK.

Fixed pressure shunts

The Parties' views

111. The Parties submitted that:

[19] In the period between 2012 and 2016, out of 37 primary neurosurgery units, **[✂]** units made purchases from both Parties in more than one year.

(a) Integra is a peripheral supplier of fixed pressure shunts, resulting in a low increment to the Parties' combined share in this product;

(b) Medtronic, the leading supplier of fixed pressure shunts, is the closest competitor to each of the Parties;

(c) Demand for fixed pressure shunts is decreasing as it is an older technology, declining from 93% of all shunts in 2000 to 53% of all shunts in 2016.

(d) Integra does not have an antimicrobial shunt catheter, which is increasingly strongly favoured among surgeons.

(e) A number of significant competitors in fixed pressure shunts will continue to constrain the Parties post-Merger.

Shares of supply

112. The Parties provided the following shares of supply by value in the UK for the past five years, noting that the shares for competitors are the Parties' best estimates. The CMA has received data on the shares of inserted (implanted) shunts in 2013 from the **[✂]**, which are presented in the last column. These figures are broadly in line with the Parties' estimates.

Fixed pressure shunts, UK						**[✂]**
	Value, £					**Volume**
	2012	**2013**	**2014**	**2015**	**2016**	**2013**
Total demand	[3-4] million	[3-4] million	[3-4] million	[3-4] million	[3-4] million	
Integra	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	**[✂]**
The Codman business	[20-30]%	[30-40]%	[30-40]%	[30-40]%	[30-40]%	**[✂]**
Combined	*[30-40]%*	*[30-40]%*	*[30-40]%*	*[30-40]%*	*[30-40]%*	**[✂]**
Medtronic	[60-70]%	[50-60]%	[50-60]%	[50-60]%	[40-50]%	**[✂]**
Aesculap/B. Braun	[0-5]%	[5-10]%	[10-20]%	[10-20]%	[10-20]%	**[✂]**
Sophysa	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	**[✂]**
Spiegelberg	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	**[✂]**
	Volume, units					
Total demand	[10-20] thousand	[10-20] thousand	[10-20] thousand	[5-10] thousand	[5-10] thousand	
Combined	*[30-40]%*	*[30-40]%*	*[30-40]%*	*[30-40]%*	*[30-40]%*	

Source: The Parties' estimates and **[✂]**. The Parties estimates for value include sales of valves, catheters and accessories; for volume estimates valves and catheters, calculated as a single unit each (eg a valve and two catheters would be counted as 3 units).

113. The table shows that the Codman business's share of supply has increased steadily over the past five years while Integra's very low share has remained stable. Post-Merger, the combined entity will have a share of approximately [30-40]%, with a [0-5]% increment.

Closeness of competition and competitive constraints

114. Third party customers generally indicated that Integra's fixed pressure shunts are viewed as old and dated. Integra does not offer an antimicrobial shunt catheter. In contrast, customers saw the Codman business as one of the market leaders in fixed pressure shunts.

115. Third parties identified Medtronic as the leading supplier of fixed pressure shunts. Two out of three hospital customers listed Medtronic as competing closely with the Codman business for these products, whilst half of competitors said Medtronic was a close competitor. The vast majority of neurosurgeons considered Medtronic to be a close competitor to the Parties for these products.

116. In addition to Medtronic, B. Braun is a supplier which has grown from a small share of [0-5]% in 2012 to [10-20]% in 2016 **[✂]**. **[✂]**. B. Braun said that it competes closely with each of the Parties for these products. Competitors of the Parties indicated that B. Braun is a close competitor of the Parties, while all neurosurgeons with whom the CMA spoke believed B. Braun to have a credible offering in competition with the Parties.

117. Some third parties also identified Sophysa and Spiegelberg as competitors, although these remain much smaller suppliers of these products.

118. The Codman business's internal documents **[✂]** focus principally on Medtronic, as well as on B. Braun's programmable valve.

119. The CMA also considered sales data provided by the Parties. The sales data indicated that the Parties compete with each other as a substantial share of customers purchased fixed shunts and related products from each of the Parties in the last five years.[20]

120. No customer of the Parties was concerned about the impact of the Merger on competition for the supply of fixed pressure shunts.

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[20] In the period between 2012 and 2016, out of 37 primary neurosurgery units, **[✂]** units made purchases from both Parties in more than one year.

Conclusion on horizontal unilateral effects in the supply of EVD collection systems

121. For the reasons set out above, the CMA believes that, while the Parties will have a relatively large share of supply in fixed pressure shunts post-Merger, the increment is small (at [0-5]%). Evidence from third parties indicates that the Parties' are not particularly close competitors for these products and they will continue to be constrained by Medtronic and, to some extent, by B. Braun post-Merger. Third party evidence also indicates that Integra's fixed pressure shunts supplied in the UK are old and dated. Accordingly, the CMA believes that the Merger does not give rise to a realistic prospect of an SLC as a result of horizontal unilateral effects in the supply of fixed pressure shunts in the UK.

Onlay and suturable dural substitutes

The Parties' views

122. The Parties submitted that there is no realistic prospect of the Merger giving rise to an SLC in relation to dural substitutes because the overlap between the Parties is limited to onlay dural substitutes and the Parties are not each other's closest competitor for this product.

123. The Parties said that **[✂]**.

Shares of supply

124. The Parties provided the following shares of supply by value in the UK for the past five years, noting that the shares for competitors are the Parties' best estimates. The CMA was not able to verify all shares with third parties, in particular prior to 2016. However, based on the Parties' calculation methodology and information provided by third parties, the CMA believes these estimates to be reasonable.

Onlay and suturable grafts, UK					
	Value, £				
	2012	**2013**	**2014**	**2015**	**2016**
Total demand	[2-3] million	[2-3] million	[2-3] million	[2-3] million	[3-4] million
Integra	[30-40]%	[30-40]%	[40-50]%	[30-40]%	[30-40]%
The Codman business	[10-20]%	[10-20]%	[10-20]%	[10-20]%	[10-20]%
Combined	*[50-60]%*	*[50-60]%*	*[50-60]%*	*[50-60]%*	*[50-60]%*
Baxter/Synovis	[20-30]%	[10-20]%	[10-20]%	[10-20]%	[10-20]%
Stryker	[5-10]%	[5-10]%	[10-20]%	[10-20]%	[10-20]%
Aesculap/ B. Braun	[10-20]%	[10-20]%	[10-20]%	[10-20]%	[10-20]%

Medtronic	[5-10]%	[5-10]%	[5-10]%	[5-10]%	[5-10]%
Tissuemed	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Medprin Redura	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
WL Gore	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
	Volume, units				
Total demand	[10-20] thousand	[10-20] thousand	[10-20] thousand	[10-20] thousand	[10-20] thousand
Combined	*[50-60]%*	*[50-60]%*	*[60-70]%*	*[50-60]%*	*[50-60]%*
Source: The Parties' estimates and third parties.					

125. The table shows that the Parties have a combined share of supply in onlay and suturable dural substitutes of approximately [50-60]% in 2016, with an increment of [10-20]%.

Closeness of competition and competitive constraints

126. The Merger will bring together the largest supplier of dural substitutes (Integra) with one of the group of next largest suppliers. While there will remain a number of other suppliers of dural substitutes, in particular Baxter, Stryker and B. Braun, these suppliers are much smaller than Integra. **[✂]**.

127. Some third parties told the CMA that the Parties are each other's closest competitor, and many identified the Parties' products as alternatives. Several third parties also identified Baxter, Stryker, B. Braun and Medtronic as alternative suppliers. Two surgeons told the CMA that there are a lot of competitors in the dural substitute market; however, one then raised concerns about the alternatives to the Parties, suggesting that very few of them have been shown to be safe.

128. One of the Parties' internal documents shows **[✂]**. This evidence suggests the Parties are each other's closest competitor.

129. The CMA considered sales data provided by the Parties. The sales data indicated that the Parties are close competitors given a substantial share of customers purchased dural substitutes from both of the Parties in the last five years.[21]

130. Several competitors raised concerns about the Merger's impact on the supply of dural substitutes. One competitor considered that the Merger would create

[21] In the period between 2012 and 2016, out of 37 primary neurosurgery units, **[✂]** units made purchases from both Parties in more than one year.

a dominant player and would make it difficult for other suppliers to compete effectively.

Conclusion on horizontal unilateral effects in the supply of onlay and suturable substitutes

131. For the reasons set out above, the CMA believes that the Parties will have a large share of supply in onlay and suturable dural substitutes post-Merger, and they may be each other's closest competitor. They will face limited competitive constraints post-Merger, with a number of smaller alternative providers. Accordingly, the CMA believes that the Merger gives rise to significant competition concerns as a result of horizontal unilateral effects in the supply of onlay and suturable dural substitutes in the UK.

Cranial access products

The Parties' views

132. The Parties submitted that:

(a) there are a large number of suppliers of cranial access products apart from the Parties which will continue to exercise a constraint post-Merger; and

(b) the Parties do not manufacture the products and acquire them from third parties.

Shares of supply

133. The Parties provided the following shares of supply by value in the UK for the past five years, noting that the shares for competitors are the Parties' best estimates. The CMA was not able to verify the shares of other suppliers but market testing confirmed that there are a large number of active suppliers.

Cranial access kit, UK					
	Value, £				
	2012	**2013**	**2014**	**2015**	**2016**
Total demand	[0-1] million	[0-1] million	[0-1] million	[0-1] million	[0-1] million
Integra	[5-10]%	[5-10]%	[5-10]%	[5-10]%	[5-10]%
The Codman business	[20-30]%	[20-30]%	[20-30]%	[20-30]%	[20-30]%
Combined	*[30-40]%*	*[30-40]%*	*[30-40]%*	*[20-30]%*	*[30-40]%*
Ethicon	[10-20]%	[10-20]%	[10-20]%	[10-20]%	[10-20]%
Medtronic	[10-20]%	[10-20]%	[10-20]%	[10-20]%	[10-20]%
B. Braun/Aesculap	[5-10]%	[5-10]%	[5-10]%	[5-10]%	[5-10]%
Stryker	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Raumedic	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Others	[40-50]%	[30-40]%	[40-50]%	[40-50]%	[40-50]%
Total demand	[0-1] million	[0-1] million	[0-1] million	[0-1] million	[0-1] million
	Volume, units				
Total demand	[10-20] thousand	[10-20] thousand	[10-20] thousand	[10-20] thousand	[10-20] thousand
Combined	*[10-20]%*	*[10-20]%*	*[10-20]%*	*[10-20]%*	*[10-20]%*
Source: The Parties' estimates.					

134. The table shows that the Parties would have a post-Merger share of supply around [30-40]% by value, with an increment of [5-10]%. Although the Codman business is the largest supplier by value, at least three other suppliers have similar shares as Integra. There is also a long list of smaller competitors for these products, with 'others' representing about [40-50]% of the total share of supply.

Closeness of competition and competitive constraints

135. The CMA's market testing confirmed that the supply of cranial access products is highly fragmented, with many firms selling products to hospitals. Customers told the CMA that they tend to acquire cranial access products separately (eg razors, syringes, needles, drapes, sponges, gauzes, swabs, ointments, hand drills, scalpels, forceps and scissors), although some acquire products in kits. As cranial access products tend to be standardised, with little differentiation and no material branding, hospitals told the CMA that they could easily switch to other suppliers without compromising patient care. While the CMA understands that the Parties supply many of the same types of cranial access products, the CMA found no evidence to indicate that the Parties are particularly close competitors. Rather, the CMA found that many competitors supply essentially identical products.

136. The CMA notes that neither Party manufacture cranial access products but rather acquire them to sell on to customers.

137. No customers or competitors were concerned about the impact of the Merger on the supply of cranial access products.

Conclusion on horizontal unilateral effects in the supply of cranial access products

138. For the reasons set out above, the CMA believes that, while the combined entity will be the largest supplier of cranial access products in the UK, the increment from the Merger will be small and the Parties will remain subject to competition from a large number of other suppliers. The CMA notes that neither party manufactures cranial access products so alternative suppliers could supply hospitals with the same products sold by the Parties. No third parties raised any concerns as a result of the Merger in relation to these products. Accordingly, the CMA believes that the Merger does not give rise to a realistic prospect of an SLC as a result of horizontal unilateral effects in the supply of cranial access products in the UK.

Barriers to entry and expansion

139. Entry, or the expansion of existing firms, can mitigate the initial effect of a merger on competition, and in some cases may mean that there is no SLC. In assessing whether entry or expansion might prevent an SLC, the CMA considers whether such entry or expansion would be timely, likely and sufficient.[22]

140. The Parties submitted that there are other neurosurgical product suppliers which would be able to expand their offerings to supply into the UK and which could enter quickly with minimal sunk costs.

141. Although the CMA found evidence that there has been some entry in the UK in the product markets where competition concerns have been identified, the CMA also found that, generally, new entrants had struggled to grow their share of supply substantially over a number of years. The Parties submitted that Raumedic and Sophysa had grown their shares significantly within five years in some products; however, the CMA was unable to confirm this.

142. The CMA notes that there appear to be significant challenges to entry and expansion in relation to the products. These include the need to build relationships with customers and the reluctance of surgeons to switch to new

[22] *Merger Assessment Guidelines*, from paragraph 5.8.1.

products. In addition, hospitals commonly do their own in-house trials of products before adopting them, increasing the barrier to switching. While these barriers may not be insurmountable, suppliers might also have limited incentives to enter, given the low available volumes and few potential customers.

143. Half of the competitors that responded to the CMA's questionnaire identified patents as a barrier to entry. **[✂]**.

144. Competitors' responses indicated that companies must invest considerable time and financial resources relative to the revenues available to penetrate these markets. For example, one competitor explained that it cost approximately £20,000 per annum for at least three years to develop a new dural substitute. Another competitor explained that the cost of attempting to enter a market with an ICP monitoring product ranged between £10,000 to £100,000.

145. While the CMA notes that there is some evidence of successful entry and expansion in some of the frames of reference, it also notes the presence of significant barriers to entry and expansion. For these reasons, the CMA has not been able to dismiss any of its competition concerns arising from the Merger on the basis that entry or expansion would be timely, likely and sufficient to prevent the realistic prospect of an SLC.

Loss of competition to innovate

146. The CMA considered whether the Merger could lessen the incentives of the merged entity to compete through innovation.

147. Neurosurgeons told the CMA that they do not believe the Parties are particularly innovative suppliers. They said, rather, innovation in the industry is mostly driven by smaller firms. One neurosurgeon explained that, as companies grow, they tend to align themselves with the US market at the expense of the needs of UK practitioners. Smaller firms, on the other hand, "tend to engage more with doctors to understand their needs in the context of bringing a new product to the market". Of the larger firms, both customers and competitors identified Medtronic and B. Braun as the strongest innovators.

148. During the course of the CMA's investigations, a few neurosurgeons noted that they perceived some of Integra's products to be old and thought that the Merger could be beneficial by encouraging Integra to improve its offering.

149. The CMA assessed the Parties' pipelines of product development and did not find evidence of additional overlaps which were sufficiently certain to raise additional competition concerns as a result of the Merger.

150. For these reasons, the CMA does not believe that the Merger will give rise to a realistic prospect of an SLC as a result of a loss of general or specific innovation.

Third party views

151. The CMA contacted customers and competitors of the Parties. No customers raised concerns regarding the impact of the Merger on competition in any of the frames of reference. However, most competitors raised some concerns about the Merger, although not all of those concerns related to competition.

152. Third party comments have been taken into account where appropriate in the competitive assessment above.

Conclusion on substantial lessening of competition

153. Based on the evidence set out above, the CMA believes that it is or may be the case that the Merger may be expected to result in an SLC as a result of horizontal unilateral effects in relation to the supply in the UK of:

- internal ICP monitoring products;
- standard EVD catheters (and standard and antimicrobial EVD catheters);
- EVD collection systems; and
- onlay and suturable dural substitutes.

Exceptions to the duty to refer

154. Where the CMA's duty to refer is engaged, the CMA may, pursuant to section 33(2)(a) of the Act, decide not to refer the merger under investigation for a Phase 2 investigation on the basis that the market(s) concerned is/are not of sufficient importance to justify the making of a reference (the ***de minimis* exception**). The CMA has considered whether it is appropriate to apply the *de minimis* exception to this case.

Markets of insufficient importance

155. In considering whether to apply the *de minimis* exception, the CMA will consider, in broad terms, whether the costs involved in a reference would be disproportionate to the importance of the market(s) concerned, taking into account the size of the markets concerned, the likelihood that harm will arise, the magnitude of competition potentially lost, the duration of such effects, and

whether the merger is one of a potentially large number of similar mergers that could be replicated across the sector in question.[23]

'In principle' availability of undertakings in lieu

156. The CMA's general policy, regardless of the size of the affected market, is not to apply the *de minimis* exception where clear-cut undertakings in lieu of a reference could, in principle, be offered by the parties to resolve the concerns identified.[24] In most cases, a clear-cut undertaking in lieu will involve a structural divestment. The CMA will not consider undertakings in lieu to be in principle available where the minimum structural divestment that would be required to ensure the remedy was effective would be wholly disproportionate in relation to the concerns identified.

157. The CMA considered whether a clear-cut undertaking in lieu would be available in this case. The Merger concerns the combination of manufacturing and other assets located outside the UK (principally in the US). Neither party manufactures their products in the UK and the rationale for the Merger is driven by US considerations. To remedy any concerns identified in the UK (which as shown below are in markets with a low aggregate value), the Parties would therefore have to divest substantial non-UK assets, which supply only a small proportion of their output to the UK. For the purposes of considering whether clear-cut undertakings in lieu are available in principle, the CMA believes that the divestments necessary to remedy its concerns would be wholly disproportionate to the concerns identified.[25]

158. Accordingly, the CMA does not consider that 'in principle' clear-cut undertakings in lieu are available in this case.

Market size

159. The CMA's guidance states that, where the annual value in aggregate of the market(s) concerned is less than £15 million in the UK, and the CMA concludes that clear-cut undertakings in lieu of reference are not in principle available, the CMA will consider whether the consumer harm caused by the merger is expected materially to outweigh the public costs of a reference.[26]

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[23] *Mergers: Exception to the duty to refer in markets of insufficient importance,* paragraphs 3 and 4.
[24] *Mergers: Exception to the duty to refer in markets of insufficient importance*, paragraph 21.
[25] For clarity, this does not mean that it would be disproportionate to accept such undertakings in lieu if offered by parties subsequent to a phase 1 decision showing that the duty to refer arises. See further *Mergers: Exception to the duty to refer in markets of insufficient importance,* paragraph 26.
[26] *Mergers: Exception to the duty to refer in markets of insufficient importance,* paragraph 28.

160. Based on the data provided by the Parties and third parties, the CMA estimated the following market sizes for the UK markets concerned:

Markets concerned	**CMA's estimate of market sizes (£)**
Internal ICP monitoring	c. £[2-3] million
Standard EVD catheters	c. £[0-1] million[27]
EVD collection	c. £[1-2]million
Onlay and suturable dural substitutes	c. £[3-4] million

161. The CMA therefore estimates that the total size in aggregate of the markets concerned is approximately £6.6 million. This is at the lower end of the £5 million to £15 million range in which the CMA will ordinarily perform a cost/benefit analysis in deciding whether to apply the *de minimis* exception.[28]

Likelihood, magnitude and durability

162. Regarding the likelihood, magnitude and durability of the SLC, the CMA notes the following:

(a) All neurosurgeons and hospitals which were contacted told the CMA that they would continue to have sufficient alternatives in each of the markets concerned after the Merger.

(b) Neurosurgeons said that they are regularly approached by firms seeking to enter or expand their product lines into different neurosurgical device markets. Although they may have limited appetite to engage with all such approaches or consider switching (due to satisfaction and familiarity with incumbent products) this would be considered if the merged entity increased its prices or worsened its product offering.

(c) In each of the markets concerned the CMA's assessment confirmed that there would be at least two other firms currently competing with the Parties.[29]

(d) Demand for neurosurgical equipment is concentrated in a small number of neurosurgical units and group purchasing organisations, which may be

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[27] The CMA's estimated size for the alternative frame of reference, standard and antimicrobial EVD catheters, is c. £**[✂]** million. On this basis, the total size of the markets concerned would be c. £**[✂]** million.

[28] *Mergers: Exception to the duty to refer in markets of insufficient importance,* paragraph 2. *E.* Where the aggregate size of the markets affected is below the £5 million threshold the CMA will generally not consider a reference to be justified.

[29] Whilst there are also suppliers active outside the UK, in particular in Europe, that could begin supplying into the UK, the CMA places limited weight on this potential constraint, in light of its findings on entry in the competitive assessment.

able to exert some buyer power were the merged entity to seek to exercise market power post-Merger.

163. The CMA believes that these factors suggest that the likelihood of any harm, the magnitude of any harm and the durability of any harm arising from the Merger will be limited.

164. The CMA also notes that the US Federal Trade Commission (**FTC**) is reviewing the Merger. **[✂]**

Replicability

165. The CMA will be less likely to apply the *de minimis* exception where it believes that the merger is one of a potentially large number of similar mergers that could be replicated across the sector in question.[30]

166. The CMA is not aware of any similar mergers in this sector and has seen no evidence to suggest that the Merger is one of a potentially large number of similar mergers that could be replicated across the sector.

Conclusion on the application of the de minimis exception

167. Taking all the above factors into consideration, the CMA believes that the markets concerned in this case are not of sufficient importance to justify the making of a reference. As such, the CMA believes that it is appropriate for it to exercise its discretion to apply the *de minimis* exception.

Decision

168. Consequently, the CMA believes that it is or may be the case that (i) arrangements are in progress or in contemplation which, if carried into effect, will result in the creation of a relevant merger situation; and (ii) the creation of that situation may be expected to result in an SLC within a market or markets in the UK. However, pursuant to section 33(2)(a) of the Act, the CMA believes that the markets concerned are not of sufficient importance to justify the making of a reference.

169. The Merger will therefore **not be referred** under section 33 of the Act.

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[30] *Mergers: Exception to the duty to refer in markets of insufficient importance*, paragraph 41.

Andrew Wright
Director
Competition and Markets Authority
6 July 2017