Medicines & Healthcare products Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom
gov.uk/mhra

[redacted]

02 May 2023

FOI **23/309**

Dear [redacted]

Thank you for your information request, dated 26th April 2023, where you asked for information relating to the Advanced Bionics HiRes Ultra and/or HiRes Ultra 3D cochlear devices which were subject to a worldwide voluntary recall on 20 February 2020.

Unfortunately, we are unable to provide the information requested, either because we do not hold it, or because the information is exempt from release under section 44. We have provided further information below on each requested piece of information.

Section 44 – Prohibitions on disclosure: the release of information is exempt as its disclosure is prohibited by other legislation. In this case, section 237 of the Enterprise Act 2002 prohibits a public authority from releasing information which came to it in connection with the exercise of its functions, and which relates to the affairs of an individual or business.

The MHRA is satisfied that the information you have requested (indicated below):

- constitutes information which came to us in connection with the exercise of the Agency's functions. The MHRA has a duty of consumer protection under the Consumer Protection Act 1987 which is listed as a specified function under Schedule 14 of the Enterprise Act 2002, and receives information while exercising consumer protection functions in its role as the regulator of medicines and healthcare products.
- relates to the affairs of Advanced Bionics, a business which continues to exist.

On that basis we are satisfied that section 44 of FOI Act applies and the information is exempt from release.

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1. This information is exempt for release under section 44.
2. Safety Public Assessment Reports are for medicines safety issues, and do not apply to medical devices such as cochlear implants. There is no similar process for medical devices, and we therefore do not hold this information.
3. The MHRA does not approve medical devices – this is done by a UK Approved Body (in the UK) or Notified Body (in the EU), and we therefore do not hold this information. This information will be held by the Advanced Bionics and their Approved Body and/or Notified Body.
4. This information is exempt for release under section 44.
5. The MHRA does not collect data on the number of patients who have been implanted with medical devices. The Independent Medicines and Medical Devices Safety Review recommended that this information be collected (see here for more information), however, many device implants, including cochlear implants, are yet to have a registry which will hold this information.
6. The MHRA does not hold this information – see point 5 above.
7. Information on the number of revisions reported to the MHRA for these devices is exempt for release under section 44.

If you have a query about the information provided, please reply to this email. For the information which is exempt for release under section 44, we could provide this information in relation to all cochlear implants, without differentiating manufacturers or brands. Please reply to this email to request this information if required.

If you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date you receive this response and addressed to: info@mhra.gov.uk

Please remember to quote the reference number above in any future communications.

If you were to remain dissatisfied with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at:

Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Yours sincerely,
Safety & Surveillance