Medicines & Healthcare products Regulatory Agency

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

[redacted]

07th November 2023

FOI **23/765**

Dear [redacted]

Thank you for your information request, dated **13th October 2023**, where you asked for:

1. *The Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED) in respect of the BHR;*
2. *Clinical Evaluation Report (CER) in respect of the BHR; and*
3. *The written report containing a critical evaluation of all the clinical investigation data held in relation to the device.*

In response to your FOI request, I can confirm that the MHRA does not hold the Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED) or the Clinical Evaluation Report (CER) in respect of the BHR.

As medical devices in the UK have their conformity assessments for CE/ UKCA mark approval conducted by an approved body, rather than the MHRA itself, it is most likely that these documents are held by the approved body. The approved body for the Smith and Nephew Birmingham Hip Resurfacing device is DEKRA Certification B.V. and I recommend that you submit a new request to DEKRA Certification B.V. for this information relating to the UK certification of the medical device.

Regarding the written report containing a critical evaluation of all the clinical investigation data held in relation to the device, we have the following questions to enable us to locate the correct report:

- What is the title of the requested report?
- When is this report dated?

I recommend that you submit a new request to the MHRA under the Freedom of Information Act 2000 including the title and date of the requested report in order for us to establish whether we hold this information. We will progress this as a new request.

We also wanted to make you aware that, if you are requesting the above in relation to gaining UK certification of the medical device, the MHRA is responsible for operating the UK medical device vigilance system. This includes carrying out market surveillance, enforcing the legislation and working in collaboration with healthcare and regulatory stakeholders both in the UK and worldwide.

However we don't directly certify medical devices, in the UK this is the responsibility of approved bodies, whom we have oversight of. In addition the MHRA have powers to remove medical devices from the UK market if we feel they are unsafe.

If you have a query about the information provided, please reply to this email

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,

FOI Team
Safety & Surveillance
Medicines & Healthcare Products Regulatory Agency
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