



Medicines & Healthcare products
Regulatory Agency

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

[REDACTED]
[REDACTED]

09 July 2024

FOI2024/00275

Dear [REDACTED],

Thank you for your information request dated 12 June 2024, in which you asked the following two questions:

1. "Did they [REDACTED] supply any form of evidence for this information [regarding the Plastibell device]?"
2. "If [REDACTED] have provided you with False or Misleading Information, which I understand is a Criminal Offence. Do you have the authority to take action against them or do I need to speak with the police with regards to this?"

The Freedom of Information Act only entitles you access to recorded information.

In response to your first question, I confirm that the MHRA does not hold any information. [REDACTED] responded to the inquiry via email. No evidence was requested, and therefore they did not provide any.

Regarding your second question, again I confirm that no relevant information is held by MHRA. This is because clinical practice issues are generally outside of our scope as we focus on regulating the safety of devices. You may consider reaching out to the Care Quality Commission (CQC) if you have not already done so, as they may be better equipped to provide further guidance on any action you wish to pursue against Bakersfield Medical Centre. Additional support on this matter may also be found from NHS Resolution.

Please note that registration of devices with the MHRA (the UK Competent Authority) does not represent any form of accreditation, certification, approval, or endorsement by the MHRA



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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,

Safety and Surveillance Group