

Press release

Date: 24 January 2007
 Time:
 Subject: 'Baby Beets Fetal Doppler' Warning

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UK medical devices regulator warns women over dodgy foetal monitor

The Medicines and Healthcare products Regulatory Agency (MHRA) is asking women not to use the 'Baby Beets Fetal Doppler' after concerns that it might not reach the required standards of safety and quality, or that it works, as required by the Medical Devices Regulations. The MHRA was alerted to the product being sold on the Internet by a legitimate manufacturer of foetal monitors. As there is no evidence that the safety and performance of this product has been assessed in accordance with the Medical Devices Regulations, the product could pose a potential risk to the mother and/or baby in respect of any energy emitted.

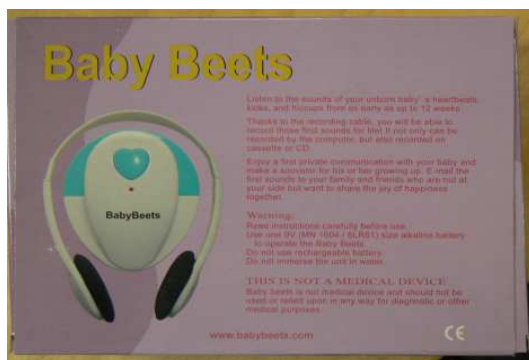
Clive Bray, Director of Device Technology and Safety at the MHRA said, "The MHRA is currently assessing certain safety aspects of the product. It must be stressed that initial indications are that the health risk to a pregnant woman and/or their baby is small. However, as a precautionary measure, I strongly urge anyone using this product to immediately discontinue use."

The MHRA has seized 113 of these products and advises people selling this product to stop and remove it from their stock.

Ends

Notes to Editor:

1. Pictures of the 'Baby Beets Fetal Doppler' are below:



2. A foetal monitor is used to detect foetal heartbeat and obtain confirmation of continued life during pregnancy.
3. In general, a medical device cannot be marketed in the UK without carrying a CE Mark of Conformity. A CE mark is applied by the manufacturer to denote that the device meets the relevant regulatory requirements and performs as intended. For all but the very lowest risk devices, such as unmedicated bandages, an EC Certificate of Conformity must be obtained from an independent certification organisation, called a Notified Body, before the CE marking can be affixed. The MHRA is responsible for designating UK Notified Bodies and regularly audits them to ensure that they continue to perform to the required standards. Foetal dopplers are a Class IIa device and would need an EC Certificate from a Notified Body. The 'Baby Beats Fetal Doppler' incorrectly claims to be CE marked and that its EC representative is Lloyds Pharmacy.
4. If people wish to send this product to the MHRA, they should send it to:
Medical Devices Compliance Unit
Medicines and Healthcare products Regulatory Agency
8/2 Market Towers
1 Nine Elms Lane
London
SW8 5NQ
5. The MHRA is the government agency responsible for ensuring that medicines and medical devices work, and are acceptably safe. No product is risk-free. Underpinning all our work lie robust and fact-based judgements to ensure that the benefits to patients and the public justify the risks. We keep watch over medicines and devices, and take any necessary action to protect the public promptly if there is a problem. We encourage everyone –the public and healthcare professionals as well as the industry – to tell us about any problems with a medicine or medical device, so that we can investigate and take any necessary action.
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