**Unsafe medical devices 'given OK by Brussels': Patients put at risk after malfunctioning defibrillators and stents that cause strokes are approved**

* **European Commission watchdog gave green light to equipment**
* **Researchers claim there is a 'lack of transparancy' in the system**
* **Unsafe breast implants also three times more likely to be approved by EU**

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* [e-mail](mailto:?subject=Read%20this:%20Unsafe%20medical%20devices%20%27given%20OK%20by%20Brussels%27:%20Patients%20put%20at%20risk%20after%20regulator%20approved%20malfunctioning%20defibrillators%20and%20stents%20that%20cause%20strokes&body=Unsafe%20medical%20devices%20%27given%20OK%20by%20Brussels%27%3A%20Patients%20put%20at%20risk%20after%20regulator%20approved%20malfunctioning%20defibrillators%20and%20stents%20that%20cause%20strokes%0A%0AResearchers%20founds%20the%20European%20Commission%20watchdog%20had%20given%20the%20green%20light%20to%20blood%20vessel%20stents%20which%20caused%20strokes%20and%20malfunctioning%20defibrillators.%0A%0Ahttp%3A%2F%2Fwww.dailymail.co.uk%2Fnews%2Farticle-3665102%2FUnsafe-medical-devices-given-OK-Brussels-Patients-risk-regulation-approved-malfunctioning-defibrillators-stents-cause-strokes.html%3Fito%3Demail_share_article-top%0A%0A%0AMost%20Read%20Articles%3A%0A%0AMum%20has%20two%20sets%20of%20twins%20despite%20using%20CONTRACEPTION%3A%20Emma%20had%20first%20surprise%20pregnancy%20while%20on%20the%20pill%2C%20then%20switched%20to%20an%20implant...%20only%20to%20conceive%20again%20and%20beat%20three-billion-to-one%20odds%C2%A0%0Ahttp%3A%2F%2Fwww.dailymail.co.uk%2Fhealth%2Farticle-4262100%2FMother-two-sets-twins-birth-control.html%3Fito%3Demail_share_article-top_most-read-articles%0A%0AMadeleine%20McCann%27s%20father%20warns%20thousands%20of%20heart%20patients%20are%20undergoing%20needless%20surgery%2C%20which%20is%20costing%20the%20NHS%20%C2%A360m%20a%20year%2C%20due%20to%20an%20inaccurate%20test%0Ahttp%3A%2F%2Fwww.dailymail.co.uk%2Fhealth%2Farticle-4263480%2FInaccurate-heart-test-costing-NHS-says-Gerry-McCann.html%3Fito%3Demail_share_article-top_most-read-articles%0A%0AA%20yawning%20gap%21%20Mums%20lose%20more%20sleep%20than%20dads%3A%20Chance%20of%20regularly%20not%20getting%20enough%20shuteye%20goes%20up%20by%2050%25%20for%20every%20child%20a%20woman%20has%0Ahttp%3A%2F%2Fwww.dailymail.co.uk%2Fhealth%2Farticle-4262502%2FA-yawning-gap-Mums-lose-sleep-dads.html%3Fito%3Demail_share_article-top_most-read-articles%0A%0A)

Patients are being harmed because the EU regulator is giving its approval to faulty medical equipment and implants used in common operations, researchers warn.

They found the European Commission watchdog had given the green light to blood vessel stents which caused strokes, devices to reduce back pain that led to fits and malfunctioning defibrillators.

They also discovered that unsafe breast implants were three times more likely to be approved by the EU than its counterpart in the US.

Researchers from Harvard University in the US and King’s College London say there is an ‘absolute lack of transparency’ in the EU’s system which is denying doctors and patients vital information about how devices were approved and the risks they carry.

They blame the shortcomings for creating the recent PIP silicone breast implant scandal, as well as the use of faulty metal-on-metal hips.

The French-made implants were never approved in the US but were given to 47,000 British women after EU approval in the 1990s.

It was later discovered they had double the rupture rate and used industrial silicone.

 The EU also gave the green light to metal-on-metal hip implants, given to up to 50,000 patients in Britain, which leach chemicals into the blood.

Dr Thomas Hwang, an expert in technology at Harvard University, said patients were being put at risk by a ‘absolute vacuum of information’ within the EU system.

He said: ‘If my surgeon was going to implant a device, I would absolutely want to know all the evidence.

‘The point of this paper was to raise concerns about the absolute lack of transparency in the EU. There isn’t any information on how a device works, evidence of benefits and also the risks.

‘Patients can’t really give informed consent as they don’t know all the risks and benefits.’

Approved medical devices in the EU are given a Conformité Européenne (CE) kitemark.

But officials do not demand to see any evidence from clinical trials carried out by manufacturers – they just ask for documents to show devices are ‘generally safe’ and work ‘as intended’.

The US system, regulated by the Food and Drug Administration, demands data from trials. Although it takes longer and devices are not available for use as quickly compared to the EU, they tend to be safer.

In Britain, the Medicines and Healthcare Products Regulator Agency regulates devices but can only recall them once safety concerns have been raised.

It does not carry out prior checks before they are used in hospital.

Peter Walsh, of patient safety charity Action Against Medical Accidents, said: ‘Medical devices are known to cause over 100 deaths a year and thousands of serious injuries.

‘Regulation and approval processes need to be improved.’

Read more: <http://www.dailymail.co.uk/news/article-3665102/Unsafe-medical-devices-given-OK-Brussels-Patients-risk-regulation-approved-malfunctioning-defibrillators-stents-cause-strokes.html#ixzz4Zt2XOCI9>   
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