EU systems to approve medical devices 'three times as risky' as in US

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The EU system for approving new medical devices is three times more risky for patients than the model used in the US, research suggests.

Products used to treat conditions such as heart problems or arthritis are far more likely to be recalled or result in a safety alert if they are put through the EU regulatory system first before going for US approval, researchers found.

They warned that patients were being put at risk by the EU system and may be misled into thinking products have been rigorously tested as safe.

In fact, many are "inadequately tested", the team from Harvard University, King's College London and Harvard Medical School said.

[Britain’s departure from the EU](http://www.telegraph.co.uk/news/2016/05/22/brexit-would-be-very-dangerous-for-the-nhs-health-service-chief/)will mean that regulatory bodies in this country will have to establish new systems to govern safety of devices.

In the current EU system, approval means products "can be marketed if they perform 'as intended' and are likely to be safe".

Clinical testing on humans may only be required for some high risk devices.

In contrast, in the US, high risk devices must demonstrate "reasonable assurance of safety and effectiveness" before they can be used by patients, and generally need to go through clinical trials on people.

The experts, writing in the British Medical Journal (BMJ), said that while products may reach patients in the EU quicker than in the US  "the possible benefits of faster access must be carefully weighed against the risks arising from devices".

They examined 206 devices approved both in the EU and the US, most of which were developed by large companies.

The vast majority were heart devices, while others were for orthopaedic problems and neurological issues.

Almost two thirds of the sample were first approved in the EU.

Overall, quarter of products were subject to a recall or post-marketing safety alert, such as a heart pumping system that was defective and could shut down without warning, and a seizure device that could actually increase the rate of seizures.

Devices approved first in the EU were associated with a 2.9-fold greater rate of safety alerts and recalls - and a 4.6-fold greater rate of recalls alone - than devices first approved in the US.

In one case, a drug-eluting stent - used to open the arteries to prevent heart attacks - received EU approval in 2006.

However, a year later the stent was recalled after a US trial showed that the device was associated with a significantly increased rates of problems, including more heart attacks.

The researchers said EU approval "may be misinterpreted as signifying that devices are safe and clinically effective".

Regulators in this country have said [Brexit could slow down access to drugs and medical devices.](http://www.telegraph.co.uk/news/2016/05/23/brexit-could-slow-access-to-new-medicines-and-delay-cure-for-can/)