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The US FDA plays it safe

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Amid a huge furore over unsafe implanted medical devices the US FDA has released new proposals that are cautious to the point of toothlessness – and wouldn't affect most implanted devices anyway.

On Monday the US FDA announced that it was considering taking steps to ensure that medical devices cleared for sale in the US via the 510(k) route were safe. Yesterday, it said the same thing all over again. Little in the announcements is new, with the agency reiterating many of the proposals outlined in its Medical Device Safety Action Plan (MDSAP), released back in April.

What is new is that the agency is considering encouraging medtech companies to use more recently approved predicate devices in their 510(k) applications. But even here the language is highly cautious, and the steps the agency plans to make are so small and tentative that it will take years for an effect to be felt in the market; even then it will be a ripple, not a splash.

Previous predicates

The FDA is simply considering publishing a list of devices whose 510(k) clearances relied on predicates that had themselves been approved more than 10 years earlier.

And that seems to be it. There is no suggestion that these devices might be withdrawn, or their manufacturers instructed to submit new applications based on more recent predicates. And even this list is still only under consideration, with the FDA to seek public feedback on whether the 10-year period is the right starting point.

Last year the 510(k) pathway was used to clear 3,173 devices, around 82% of all the medical devices the FDA regulated. Between 2015 and 2018 around 20% of these clearances relied on predicates more than 10 years old. The FDA makes it very clear that it does not believe that these products are unsafe, but says it is "concerned that this practice of relying on predicates that are old, and may not reflect modern performance characteristics, means that some devices are not continually improving".

Industry watchers might be forgiven for harbouring suspicions that the timing of the FDA's announcements might be somehow linked with the uproar about unsafe implanted devices following an investigation by the International Consortium of Investigative Journalists. The agency merely says that the announcements follow the closing of the public comment period and its review of the feedback on the MDSAP.

High risk

In any case few implanted devices undergo review under 510(k), which may only be used by devices believed to pose a low risk to patient health. High-risk devices must run the gauntlet of the FDA's more stringent premarket approval (PMA) path, and this includes several highlighted by the ICIJ's reporting.

For example Essure, the Bayer contraceptive device that has been linked to horrendous side effects and was eventually withdrawn from market, underwent the strictest possible checking by the FDA. In July 2002 it was scrutinised by an advisory committee which recommended approval; the PMA was duly granted in November of that year.

If the strictest scrutiny the FDA can bring to bear on medical devices cannot guard against patients being harmed, it is worth asking how much tinkering around at the edges of the low-risk 510(k) path can actually achieve.

The FDA wants to bar the sale of unsafe devices more effectively than it has in the past, while simultaneously getting new products on the market faster than ever before. Without a vast increase in budget and headcount it is hard to see how it can do both.