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CE Mark vs FDA Approval?
Medical Devices Group on LinkedIn
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Medtech enthusiast, ambitious doer, and resident contrarian. That's me. In an effort to learn from dynamic experts in the medtech space, I founded Medsider.com. I work (and have worked) for some of the largest medical device companies in the world. After plenty of wins and losses, Medsider.com is the site I wish I had from the beginning.

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“Learning is not a product of schooling, but a lifelong attempt to acquire it.”

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With the ever-increasing stringency, time, and expense associated with FDA approval for medical devices, debate is sharpening in the medical devices industry over whether it is actually better business strategy to prioritize getting a CE mark for your product.

This article gives an overview of a recent iteration of a robust debate within the Medical Devices Group on LinkedIn which asked “Is a CE mark good enough?”

This was by no means universally agreed upon by those involved in the discussion, which tended to gravitate around a few key topics:

1. **Is FDA Approval Directly Comparable to the CE Mark?**
   
   A few participants pointed out the aims and methods of a FDA approval are actually quite different to the CE mark, which is sometimes disparaged as "what they use to approve Chinese toys."

   Indeed, Michael Olmsted said:

   "'In my past medical device experience as a US-based manufacturer, we didn't really compare CE and the FDA but whether your equipment was UL (Underwriters Laboratory) certified and then CE approved to be sold into Europe. FDA approval seemed to be more outcome-based..."

   David Gray cut to the heart of this distinction:

   "'The EU applies the CE Marking process primarily to ensure safety, as well as a reinforced manufacturer obligation with respect to device claims. The FDA does this too, but has the additional constraint of evaluating efficacy, which is indirectly but ultimately linked to healthcare reimbursements. In other words, both systems are set up to ensure patient/user safety and to enforce a device does what it says it's meant to do, with the FDA looking at the wider picture and asking 'Does healthcare really need this?'"

   This was also brought up in the context of the recent PIP breast implant scandal in Europe, where thousands of women are at risk of permanent injury from faulty implants that had CE marks. This brings us on to the next topic:
What Can We Learn from the PIP Scandal?

There was ambivalence among participants over how the FDA approval process prevented the PIP scandal from erupting in the US.

Jean Bigoney reckoned it did indeed save lives:

"Make no mistake, someone determined to substitute inexpensive non-approved materials for costlier approved ones could get away with it in the US, at least for a limited period of time. However I like to think that sooner or later, they would be on the FDA radar. As a matter of fact, in the case of PIP, the FDA inspected the manufacturing site way back in 2000 in connection with a different type of breast implant and as a result sent PIP a warning letter."

The same commenter went on to question how PIP managed to fly under the radar for so long in Europe, and mentions that these implants didn't receive PMA in the US. However, the European approval process does receive some defense.

John Beasley, who has worked on the regulatory process in Europe, says

"The conclusion is best stated by John Brennan in this blog: '...the PIP case is one of alleged fraud. No system can ever fully guard against deliberate criminal activity.' He also compared the 510(k) clearance unfavorably with FDA equivalents, because:

"The EU Directives for medical devices (AIMD, MDD and IVD) all require the manufacturer to "pass" a quality management system assessment prior to issuance of an EC Certificate while FDA clearance through the 510(k) program does not. FDA inspects to 21 CFR 820 sometime after 510(k) clearance is given and devices are on the market sometimes as much as years afterwards."

However, none of this addresses a factor high in the medical device professional's mind – COST."
Which Offers More Bang for Your Buck?

The answer to this question depends in no small part on what class of medical device you plan on marketing. Gordon McKenzie, whose start-up sells a Class II imaging device, said there wasn't much difference between obtaining a 510(k) and a CE mark:

"We found a regulatory advisor whose entire purpose was to make things as simple as possible. He stressed that all either system wants is complete, accurate information covering all the points needing addressed. He advocated using the 510(k) submission as a template, as if a submission covered every single point competently, then there would be little work to get the CE mark on top of this. We had no problems in getting a CE, at all, and we got our 510(k) in less than six weeks from initial submission."

However, the situation was different for Class III devices that require PMA from the FDA. Although CE marks are easier to acquire for these devices, this is only half the battle, as Dr. Thomas Degen related:

"Having the CE is only half way for a Class III device. You will need reimbursement for every single country; that is where the advantage goes back to the American system."

Given all EU countries have their own healthcare administration, a company marketing a Class III device needs to gain approval from every European country's regulatory body independently. FDA approval is applicable in all 50 states.
Time is of the Essence…

Although the choice between the two regulatory processes may seem unclear, with each holding advantages over the other in different circumstances, there is one area where the European process holds a clear advantage: speed of approval. This is the case to the extent that Brian Buntz mentioned that the director of the CDRH, Jeffrey Shuren, said the European public is treated like "guinea pigs" in testing new devices.

However, the consensus seemed to be that the safety records of the two regulatory processes was comparable, and the FDA approval delay was really down to bureaucracy. Thomas Z. Lauritzen made it plain:

"Since FDA approval has more hoops to jump through, most companies are applying and going through the CE process first. One has to be last, and at least CE has clear rules and you're not subjected to whatever whim the FDA comes up with every day of the week."

He then explained:

"There's a lot of pull right now making the FDA process more streamlined (like the CE) because the rule of thumbs is that FDA approval for medical devices is 4 years later than CE. (Part is because many apply for FDA after CE though). A main selling point is that this delay is preventing safe treatments for Americans. A big example is some heart stent (forgot the company) that is estimated could have saved 100,000 Americans in the 4 years between CE and FDA approval."

Conclusion

For many medical device companies, attempting both FDA approval and European approval simultaneously is just too much hassle. From what this discussion tells us, it seems Class I and II devices have a global advantage in obtaining CE mark certification first, whereas Class III devices may gain a market advantage in attempting PMA first.
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