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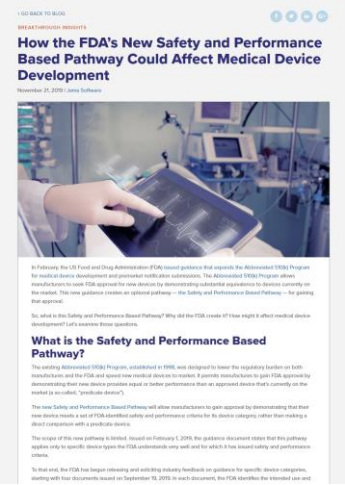
PROJECT **Blog post: FDA Safety and Performance Based Pathway**

OBJECTIVE **Attract traffic and readership with an informative post, as well as nurture leads in the medical devices sector.**

COPY EXCERPT

How the FDA's New Safety and Performance Based Pathway Could Affect Medical Device Development


How the FDA's New Safety and Performance Based Pathway Could Affect Medical Device Development

What is the Safety and Performance Based Pathway?

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In February, the US Food and Drug Administration (FDA) issued guidance that expands the Abbreviated 510(k) Program for medical device development and premarket notification submissions. The Abbreviated 510(k) Program allows manufacturers to seek FDA approval for new devices by demonstrating substantial equivalence to devices currently on the market. This new guidance creates an optional pathway — the Safety and Performance Based Pathway — for gaining that approval.

So, what is this Safety and Performance Based Pathway? Why did the FDA create it? How might it affect medical device development? Let's examine those questions.

What is the Safety and Performance Based Pathway?

The existing Abbreviated 510(k) Program, established in 1998, was designed to lower the regulatory burden on both manufactures and the FDA and speed new medical devices to market. It permits manufactures to gain FDA approval by demonstrating their new device provides equal or better performance than an approved device that's currently on the market (a so-called, "predicate device").

The new Safety and Performance Based Pathway will allow manufacturers to gain approval by demonstrating that their new device meets a set of FDA-identified safety and performance criteria for its device category, rather than making a direct comparison with a predicate device.

The scope of this new pathway is limited. Issued on February 1, 2019, the guidance document states that this pathway applies only to specific device types the FDA understands very well and for which it has issued safety and performance criteria.

To that end, the FDA has begun releasing and soliciting industry feedback on guidance for specific device categories, starting with four documents issued on September 19, 2019. In each document, the FDA identifies the intended use and design characteristics of the device class along with the testing performance criteria for the class. The four device types for which the FDA has issued guidance are:

1. Conventional Foley catheters
2. Cutaneous electrodes for reporting purposes
3. Orthopedic, non-spinal, metallic bone screws
4. Spinal plating systems

The FDA plans to expand the program by rolling out many more such documents in the coming months.