

• The **REFERENCES** to this article are available at:
www.myendosite.com/htmlsite/2009/refs78909.pdf

• **NOTE:** Pages **18S₁** and **18S₂**—which include two important **BOX ARTICLES** and **TABLES 1 AND 3**—were not included in the mailed version of this newsletter, but are attached and available *only* in this **on-line** version.

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Thank you for your interest in this newsletter. *I have addressed each issue and topic to the best of my ability. Respectfully,* **Lawrence F. Muscarella, Ph.D.**
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Box. What is a 510(k) clearance, PMA?

A *510(k) clearance* – named for the provisions detailed in *section 510, item k* of the Medical Device Amendments (1976) to the *Federal Food, Drug, and Cosmetic Act*^{15,79} – is an order issued by the FDA, in the form of a letter, granting a manufacturer the clearance, or legal right, to market (and introduce into interstate commerce for commercial distribution) many types of medical devices.⁸⁰ Among other satisfied criteria, devices that receive a 510(k) clearance have been determined by the FDA to be *substantially equivalent* to a legally marketed device known as the *predicate*.

In contrast, a *premarket approval*, or PMA, is a more rigorous scientific clearance granted by the FDA to a manufacturer who has demonstrated, using scientific and clinical data, that its medical device is safe and effective (as opposed to being merely substantially equivalent to a predicate device).^{80,81} Whereas most *class II* devices enter the market by way of a 510(k) clearance, *class III* devices generally require a PMA.⁷⁹⁻⁸¹

Briefly, medical devices are classified by the FDA into one of three *classes*, based on risk and the level of regulatory controls necessary to ensure their safety and effectiveness.⁸⁰ *Class I* medical devices, for example, pose the lowest risk of patient injury, and therefore typically receive minimal regulatory control and oversight. These devices generally require neither a 510(k) clearance nor a PMA prior to their marketing.⁸⁰ A tongue depressor is an example of a *class I* device.

A *class II* device generally requires more regulatory control, and an application for its 510(k) clearance typically includes, not usually data from clinical studies, but rather performance comparisons and bench-testing data. A steam sterilizer and an automated endoscope reprocessor are examples of *class II* devices. That a 510(k) clearance may not always be sufficiently rigorous to ensure patient safety is a topic of current debate.

Generally requiring a PMA and accompanying clinical data, *class III* devices pose the most potential for patient injury and, therefore, receive the FDA's most rigorous control and premarket scrutiny.^{80,81} A permanent implant is an example of a *class III* device. •