

Box. What is an “investigational” device?

On occasion, a legally marketed medical device—such as the Abtox Plazlyte System—may be determined by the FDA to have been modified and to be significantly different from the model the FDA originally cleared by way of the 510(k) process. Examples of such modifications include significant design and engineering changes, a change in the device's intended use, and, for instance, the re-formulation of a liquid sterilant.¹³

Such significant modifications render the device's original 510(k) clearance no longer applicable, causing the device to be *misbranded*.^{13,82} Indeed, as the FDA acknowledges,¹³ the safety and effectiveness of misbranded devices cannot be assured, ordinarily resulting in their removal from the U.S. market. Notably, the Food Drug and Cosmetic Act (the “FD&C Act”) prohibits such modified devices from being marketed and introduced into interstate commerce—that is, to be sold, shipped, and commercially distributed within the U.S.—until the modified device receives from the FDA a new 510(k) clearance (or a premarket approval, or PMA).¹³

The FD&C Act acknowledges that the discontinued use of a faulty device can at times interfere with patient care. To temper this circumstance, the FD&C Act insightfully provides an “investigational device exemption,” or IDE,⁷⁴ that legally permits the clinical use of an otherwise unapproved device.

In short, an IDE allows the manufacturer of an unapproved device—considered “investigational”

because it lacks a requisite 510(k) clearance or PMA¹⁷ (and is not otherwise exempted from either)—to circumvent legally the FD&C Act's prohibition on the introduction of an unapproved device into interstate commerce (refer to this newsletter's main article, p. 14). Indeed, an IDE may be used by manufacturers of unapproved (and not yet legally marketed) devices to acquire, in support of a PMA application (and, infrequently, a 510[k] application), the clinical data necessary to demonstrate that the device is both safe and effective when used in accordance with its labeling.

Nevertheless, because the safety and effectiveness of investigational devices cannot be assured,¹⁷ the FD&C Act requires that several criteria be met and measures be in place to reduce the risk of an adverse patient outcome. Among other stipulations, an approved IDE requires that an “institutional review board” (IRB) be established to oversee and monitor the investigational device's clinical use.⁷⁴ In addition, the FD&C Act requires that the device display the labeling: “Caution – investigational device” and that informed patient consent be obtained before its use.^{74,75}

In summary, the FDA's warning letter (*refer to*: this newsletter's main article)^{13,21,22}—which concludes that the model of the System 1 that has been sold since 1988 is: significantly modified; an adulterated and misbranded device whose safety and effectiveness cannot be assured; and without regulatory approval or an approved IDE (refer to [Table 3](#), below)—would seemingly suggest that the FDA might consider the System 1 to be an investigational device.^{13,17,74,75}

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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- 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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