

• 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.

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: Might the FDA clear an “updated” System 1?

In January, 2009, Steris submitted to the FDA a modified, if updated, model of the System 1 labeled both to achieve “liquid sterilization” and to produce “sterile” filtered water from a tap.^{21,22} (The manufacturer also likely submitted an application to the FDA to market an accompanying biological indicator, or BI, as required to monitor the peracetic acid’s effectiveness, as well as presumably having submitted an application to market a different type of BI for monitoring and verifying the “sterility” of the rinse water.)

A fair question to ask is whether the FDA might issue a 510(k) clearance to Steris for this updated System 1 model. Although conjecture, the answer to the question would appear to be in the *no*, because the inherent limitations of liquid sterilants and bacterial water filters do not support the validity of a “liquid chemical sterilization” claim. And, because no other device with similar claims to the System 1 is legally marketed, no predicate device demonstrated to be substantially equivalent to the updated model is available. Whether the censured System 1 (which is not legally marketed¹³) can be used as the predicate for this updated System 1 model is unclear.

Steris might consider for this updated System 1 three claims that are scientifically sound and, therefore, likely to be more palatable to the FDA. **First**, this device would be labeled as “sporicidal,” as opposed to claiming to achieve “liquid sterilization”—an important difference with a regulatory distinction. **Second**, this device would claim to rinse the endoscope with “bacteria-free” (not “sterile”) water. And, **third**, this device would be labeled to require terminal drying of the endoscope’s internal channels (using 70% isopropyl alcohol) after the completion of *each* cycle.

Because it appears that no legally marketed predicate device labeled to achieve “liquid sterilization” is available, it is also possible that the FDA might require this updated System 1 to receive a **premarket approval (PMA)** instead of a **510(k) clearance**, the former of which is a considerably more formidable, time-consuming, and expensive application. Yet, the System 1 was cleared in 1988 for “liquid sterilization” and the production of “sterile” water. So, that the updated System 1 might, too, be cleared with these two claims remains a possibility. ●