

# The Q-Net™ Monthly

Volume 6, Number 7

July 2000

## Reusing disposables

Proponents of reusing disposable items may contend that this practice is safe, because data showing it poses a risk are lacking. In the July 2000 issue of *Infection Control and Hospital Epidemiology*, researchers report a pseudo-outbreak caused by the reuse of disposable stopcocks during bronchoscopy. Underscoring the potential for patient injury, this report notes that most clinical studies evaluating the safety of reusing disposable items “lack the statistical power to detect small but potentially clinically important outcomes.” In truth, the lack of data linking this practice to patient injury does not affirm the absence of a risk.

## Editor-in-Chief

**Lawrence F Muscarella, PhD**  
Chief, Infection Control  
Custom Ultrasonics, Inc.  
Ivyland, PA 18974

## What is ‘Q-Net’?

**Q-Net** is a technology-assessment network of questions and answers. Its newsletter is *The Q-Net™ Monthly*.

**Q-Net’s** main goal is to encourage the infection control and endoscopy communities to not only ask good questions but to also demand succinct and well referenced responses.

**Q-Net** addresses the needs of both the health care provider whose goal is to provide the best care possible, and the patient who deserves affordable quality health care.

## What is a ‘510(k)’?

*Hospitals and third party companies reprocessing disposable items for reuse will soon be required to comply with all of the FDA’s rules and regulations that govern manufactures of medical devices.*

**Food, Drug and Cosmetic (FD&C) Act:** The Federal Food, Drug, and Cosmetic (FD&C) Act is a law that, in part, requires that medical devices sold in the United States be safe and effective. The Food and Drug Administration (FDA) is responsible for developing the policies required to enforce the FD&C Act’s provisions. While they are not necessarily stated explicitly in this act, the FDA’s rules and regulations have the same effect as law. (The FDA’s final regulations are codified annually in the Code of Federal Regulations. Most of the FDA’s device regulations are in Title 21 CFR Parts 800-1299; refer to: “<http://www.fda.gov/cdrh/devadvice/800to1299.html>”.)

In accordance with its legal authority, the FDA requires manufacturers of medical devices to comply with all of its rules and regulations, including registration, medical device reporting, good manufacturing practice requirements, and premarket notification and approval requirements. These requirements must be satisfied before a manufacturer can market (or otherwise introduce) a medical device into interstate commerce for commercial distribution in the US.

Understanding what defines a *manufacturer* subject to all or some of the FDA’s regulations can be confusing (as recently demonstrated by the FDA’s well-publicized efforts to regulate cigarette companies). The FDA’s policy of *regulatory discretion*, which allows it to use its judgment in prioritizing and optimizing its limited resources, can further confound the inexperienced.

For instance, the FDA has legal authority to regulate as manufacturers third-party companies that reprocess disposable devices for reuse. Nevertheless, the FDA has not actively required these companies to comply with all of its regulations. Like manufacturers, third party reprocessors are required to register with the FDA. But unlike manufacturers, third party reprocessors have not been required to comply with the FDA’s premarket notification regulations.

Similarly, the FDA’s current regulatory policy does not provide active oversight of hospitals that reprocess disposable devices for reuse, notwithstanding its apparent legal authority to do so. Such apparent inconsistencies in the active enforcement of its rules and regulations have caused the FDA to reevaluate its current policies and consider new strategies that minimize, if not eliminate, the appearance of multiple standards.

Therefore, due in part to: (1) reports suggesting an increase in the practice of reprocessing disposable devices for reuse; (2) recent media reports discussing the potential for the reuse of disposable devices to cause serious patient injury; and (3) potential inadequacies and inconsistencies in its enforcement of facilities that reprocess disposable devices for reuse, the FDA has concluded

*(Continued on page 14)*

that more active and uniform oversight of third party companies and hospitals reprocessing disposable devices is needed.

**Reprocessing disposable devices:** According to the FDA, third-party companies and hospitals that reprocess disposable devices are manufacturers, having re-labeled these devices for reuse. Therefore, using the FDA's existing medical device classification scheme listed in the CFR (ie, class I, class II, class III), the FDA intends to regulate as manufacturers third-party companies and hospitals that engage in this practice. This new FDA policy will be phased in within the next 6 to 18 months, depending on the device's classification (*see: <http://www.fda.gov/cdrh/comp/guidance/1168.pdf>*).

As manufacturers, both third-party companies and hospitals that reprocess disposable medical devices will be actively required to comply with all of the FDA's applicable regulations, including premarket notification. Many hospitals that might be considering reprocessing disposable items for reuse may now disallow this practice, because satisfying the FDA's premarket notification requirements is likely to demand too much expertise and be too problematic, laborious, and costly. (*Note: At this time, the FDA's enforcement of premarket notifications will apply only to third party and hospital reprocessors. The FDA will exempt from its oversight "health care facilities that are not hospitals."*)

➔ **What exactly is a '510(k)? What is a 'premarket notification'? Are they the same?**

The term *510(k)* refers to the specific section of the FD&C Act that requires a company subject to this law to notify the FDA at least ninety days before marketing a medical device. In practice, this term may be used to refer to the notifying document, or *premarket notification*, that a manufacturer submits to the FDA for regulatory review prior to marketing its device. The term *510(k)* may also be used to describe the *process* of preparing and submitting the premarket notification to the FDA. Manufacturers often use this term informally to describe the FDA-signed letter granting them the legal right to market their devices, as in the expression: "Our company's device recently received its 510(k)."

As prescribed by the FDA, the premarket notifying document submitted by the manufacturer is required to include such information as the device's intended use and proposed labeling, as well as a detailed discussion of the device's similarities and differences to a comparable medical device, known as the *predicate* device, that is already being legally marketed in the US (and presumably has already been

shown to be safe and effective).

**Substantial equivalence:** In short, the intent of the FDA's 510(k) regulation is to require a manufacturer to demonstrate that its device is *substantially equivalent* to (that is, is as safe and effective as) the predicate device. If after reviewing the 510(k) submission the FDA agrees that the device is substantially equivalent to the predicate device, then the manufacturer can market legally its medical device in the US.

If, however, the FDA declares the device to be not substantially equivalent to the predicate device, then the manufacturer has a limited number of options, one of which is to seek instead for the device a *premarket approval* ("PMA"). Whereas the 510(k) process requires demonstration of substantial equivalence to a predicate device, the PMA process, which is used for a device that does not have a predicate device, requires demonstration of the device's safety and effectiveness. The PMA process is considerably more burdensome and time-consuming than demonstrating substantial equivalence to a predicate device.

**Point of clarification:** Some of the public not experienced with the FDA's premarket notification regulation may conclude (erroneously) that a device that has received a 510(k) has been "approved" for use or endorsed by the FDA. Not true. The FDA only "clears" devices for marketing, based on the information the manufacturer provided in the premarket notification - the FDA does not approve devices.

Moreover, some may conclude (erroneously) that all devices legally on the market have been subjected by the FDA to a series of rigorous and comprehensive tests designed to confirm the accuracy of the manufacturer's submitted data, conclusions, and claims. Again, not true. Although such a policy of "checks and balances" would minimize the likelihood of adverse patient outcomes, performing tests to evaluate the veracity of a 510(k) submission is not a routine FDA practice. Nevertheless, before a hospital purchases a device, requesting from its manufacturer a copy of the device's 510(k) application, when applicable, is recommended. This information will likely clarify for the hospital each competing device's specific claims, advantages and limitations.

**Copyright © 1995-2000.** All rights reserved. *It is a violation of federal copyright laws (17 U.S.C. Sec. 101 et seq.) to copy, fax, or reproduce any portion of this newsletter without the consent of Custom Ultrasonics, Inc. Q-Net is a registered trademark of Custom Ultrasonics, Inc.* v8\_july00.

Thank you for your interest in this newsletter. *I have addressed each issue to the best of my ability. Respectfully, the Publisher: Lawrence F. Muscarella, PhD.* Please direct all correspondence to:

**Lawrence F Muscarella, PhD**  
Director, Research and Development  
Chief, Infection Control



**Custom Ultrasonics, Inc.**  
144 Railroad Drive Ivyland, PA 18974  
Tele: 215.364.8577; Fax: 561.258.8051

E-mail: [q-net@email.msn.com](mailto:q-net@email.msn.com)

