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MANUFACTURERS  
ASSOCIATION

Serving the Innovator and Entrepreneur in the Medical Device Industry

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Dockets Management Branch  
Division of Management Systems and Policy  
Office of Human Resources and Management Services  
Food and Drug Administration  
5630 Fishers Lane, Room 1061 (HFA-305)  
Rockville, Maryland 20852

**Subject: Docket No. 00D-0053 – Enforcement Priorities for Single-Use Devices  
Reprocessed by Third Parties and Hospitals**

Dear Sir or Madam:

The Medical Device Manufacturers Association (MDMA) appreciates this opportunity to comment upon the draft guidance document above referenced. MDMA, based in Washington, D.C., is the national association for the innovators and entrepreneurs in the medical device industry. Representing 130 independent manufacturers of medical devices, diagnostic products, and health care information systems, MDMA seeks to improve the quality of patient care by encouraging the development of new medical technology and fostering the availability of beneficial innovative products in the marketplace.

MDMA supports the Food and Drug Administration's (FDA's) plan to enforce the Federal Food, Drug, and Cosmetic Act (the Act) by requiring hospitals and "third parties" to submit premarket notifications (510(k)s) and premarket approval applications (PMAs) before they reprocess previously used single-use devices for subsequent use. MDMA's comments will focus on subsections 6 and 7 of section E of the draft guidance document, which outlines the FDA's priorities and plans regarding labeling and premarket review of reprocessed single-use medical devices.

**Labeling**

With respect to labeling, the FDA must require reproducers to include in their labeling and related materials a statement that cautions the user that the device has been reprocessed. This is imperative in situations in which the original manufacturer's name, trademark, or other identifying information remains on or with the device. To fail to do so would be false and misleading, and such devices should be considered as misbranded according to the explicit language in the Act.

Complete and precise labeling is a general control that the FDA should not phase in. By reprocessing and relabeling, the reprocessor is making a new claim that the reprocessed single-use device is in fact "reusable." Prudent oversight of labeling of reprocessed devices should be

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implemented as soon as possible and should cover such important labeling considerations as indications, contraindications, warnings, and proper instructions for "reuse."

### **Premarket Requirements**

#### *Determination of, and Data Needed to Demonstrate, "Substantial Equivalence"*

For all devices, included reprocessed single-use devices, the FDA may issue an order of substantial equivalence only upon making the determination that the device in question has the same intended use as the claimed predicate device and is as safe and effective as a legally marketed device.

With respect to intended use, MDMA recognizes that the Food and Drug Administration Modernization Act of 1997 (FDAMA) limited the determination of the intended use of a device that is the subject of a premarket notification to the proposed labeling contained in the submission. "Labeling" is defined under law as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." [21 U.S.C. 201(m)]. The FDA requires the submission of proposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for use in a 510(k) for review during the substantial equivalence determination.

Based on their advertisements and other promotional activity, which falls within the definition of "labeling," companies that reprocess single-use medical devices clearly intend for their reprocessing activities to enable these used single-use devices to be reused on different patients. This change in the intended use of these devices -- from single-use to multiple-use -- should require reproducers to submit premarket notification of their intent to market such devices for multiple reuse.

With respect to safety and effectiveness, FDAMA did not significantly alter the definition of "substantial equivalence" or the burden of proof that lies upon the sponsor of a device:

(i)(1)(A) For purposes of determinations of substantial equivalence under subsection (f) and section 520(l), the term "substantially equivalent" or "substantial equivalence" means, with respect to a device being compared to a predicate device, that the device has the same intended use as the predicate device and that the Secretary by order has found that the device --

- (i) has the same technological characteristics as the predicate device,  
or
- (ii) (I) has different technological characteristics and the information submitted that the device is substantially equivalent to the

predicate device contains information, including appropriate clinical or scientific data if deemed necessary by the Secretary or a person accredited under section 523, that demonstrates that the device is as safe and effective as a legally marketed device, and

(II) does not raise different questions of safety and effectiveness than the predicate device.

(B) For purposes of subparagraph (A), the term "different technological characteristics" means, with respect to a device being compared to a predicate device, that there is a significant change in the materials, design, energy source, or other features of the device from those of the predicate device.

[21 U.S.C. 513(i)]

Regardless of whether the intended use of the device to be marketed is the same as or different than the intended use of the predicate device, the Act also requires the sponsor of the device to demonstrate safety and effectiveness through comparison with the claimed predicate device. MDMA fails to see how a reprocessor could legitimately claim that a previously used and reprocessed single-use device meets the criterion in clause (i), *i.e.*, that the device "has the same technological characteristics as the predicate device," because use and subsequent reprocessing, by their very nature, affect the device's materials, performance, and sterility. A used and reprocessed device cannot possibly be considered to share the "same technological characteristics," as defined by law, as a new single-use device.

Therefore, the reprocessor must meet the two-pronged test in clause (ii), which requires the reprocessor to submit information that demonstrates the device is as safe and effective as a legally marketed device and does not raise different questions of safety and effectiveness. This test is more subjective than the standard in clause (i), but it clearly requires reprocessors to submit scientific information to prove their claims of safety and effectiveness.

This information should include, but should not be limited to, the following types:

- testing of device performance that demonstrates that the used device can be reprocessed in a manner that meets the test in clause (ii);
- assurance of the quality of reprocessing methods, including cleaning, repair, disassembly, packaging, and sterilization;
- testing to intended use parameters after re-processing;
- testing of the sterility assurance level;
- testing of the integrity of sterile packaging for the established and labeled expiration date;

- lot tracing for recall of devices that may be found in non-compliance to the FDA's Quality System Regulation; and
- labeling that clearly distinguishes the reprocessed device from the original single-use device, including appropriate warnings to the user to minimize confusion and assign liability.

Finally, the FDA should require reprocessors to include the name of the original manufacturer's product, the model number, and a description thereof in the 510(k) summary of safety and effectiveness that is required as part of the premarket notification process [21 CFR 807.92].

*Premarket Notification Requirements for Reprocessed Single-Use Devices in Exempt Device Classifications*

MDMA believes the relevant federal regulations, cited below, compel the FDA to call for premarket submissions from any person who would reprocess a single-use device for further use, whether or not the original single-use device is classified as being exempt from premarket review:

(a) Except as provided in paragraph (b) of this section, each person who is required to register his establishment pursuant to Sec. 807.20 must submit a premarket notification submission to the Food and Drug Administration at least 90 days before he proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use which meets any of the following criteria:

...

(3) The device is one that the person currently has in commercial distribution or is reintroducing into commercial distribution, but that is about to be significantly changed or modified in design, components, method of manufacture, or intended use. The following constitute significant changes or modifications that require a premarket notification:

- (i) A change or modification in the device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process.
- (ii) A major change or modification in the intended use of the device.

[21 CFR 807.81(a)]

The FDA has published relevant guidance that elaborates upon this subject, particularly "Deciding When to Submit a 510(k) for a Change to an Existing Device," issued January 10, 1997. The guidance document lists numerous questions that a person should consider when determining whether planned changes to an existing device necessitate the filing of a premarket submission. For instance, the guidance document suggests that a common labeling change that impacts intended use and would usually require submission of a 510(k) is the "reuse of devices previously labeled 'single use only'." Other questions include

- Are clinical data necessary to evaluate safety and effectiveness for purposes of determining substantial equivalence?
- Do results of design validation raise new issues of safety and effectiveness?
- Has there been a change in sterilization?
- Has there been a change in performance specification of the device or in the sterility assurance level attained as a result of the change in sterilization?
- Is this a change in the type of material from which the device is manufactured?
- Will the material of the affected part of the (non-implant) device be likely to contact body tissues or fluids in vivo?
- Is there a change in performance specifications? and
- Is this a change in the formulation of the material, but not a change in material type?

MDMA believes it would be impossible to reprocess a single-use device for further use without raising one or more of these questions, which suggests that all reprocessed single-use devices should be subject to premarket review. However, we recognize that the FDA has identified many devices that are exempt from premarket review as being "commonly" reprocessed. These exemptions should not pertain automatically to reprocessed versions of single-use devices.

The FDA has evidence in its possession that demonstrates that the reprocessing of certain single-use devices raises questions regarding the safety and effectiveness of the reprocessed device. External studies and the FDA's own investigations have shown that reprocessing a single-use device for further use can change the device's performance specifications, the device's sterility assurance level, and the integrity of the device's materials, to name three possible outcomes. The FDA, in its companion draft guidance document outlining its "review prioritization" scheme, even acknowledges that certain single-use devices exempt from premarket review nevertheless present a high risk to the public health when reprocessed and reused.

For the reasons cited in this section, then, the FDA should require anyone who reprocesses a single-use device for subsequent use to file a premarket notification with the FDA, regardless of whether the device is classified as exempt from premarket review.

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Again, MDMA appreciates the opportunity to comment on this draft guidance document, and we look forward to continuing to work with the FDA to protect and promote the public health through innovation in medical technology.

Very sincerely yours,



Stephen J. Northrup  
Executive Director

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