



Medtronic

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April 7, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 10-61
Rockville, MD 20852

Subjects:

**Reprocessing and Reuse of Single-Use Devices: Review Prioritization
Scheme as released for comment on February 8, 2000, Docket No. 00D-0053**

**Guidance for Enforcement Priorities for Single-Use Devices Reprocessed by
Third Parties and Hospitals, released for comments February 8, 2000,
Docket No. 00D-0053**

Dear Sir or Madam:

Medtronic, Inc. submits the attached comments on the above referenced documents.

Medtronic, Inc., headquartered in Minneapolis, is the world's leading medical technology company, specializing in implantable and interventional therapies that restore health, extend life and alleviate pain. Medtronic, Inc.'s operations are primarily focused on providing therapeutic, diagnostic and monitoring systems for cardiac rhythm management, cardiovascular, neurological, and spinal markets that in 1999 benefited over 1.5 million patients worldwide.

In general, Medtronic supports the approach to enforcement that these documents describe. However, Medtronic urges the FDA to give prominent consideration to the risks that result from uncontrolled processes including device use and recovery in determining priorities. Medtronic also urges the FDA to review the labeling provided by third party reprocessors immediately and not wait until premarket notification/approval requirements are enforced.

00D-0053

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There are important aspects of the proposals that are deficient in regard to these concerns. The deficiencies are explained in the attached comments.

Medtronic appreciates the opportunity to comment on these documents.

Sincerely,

A handwritten signature in black ink that reads "C. Whitacre". The signature is written in a cursive style with a large initial "C" and a distinct "Whitacre" following.

Chip Whitacre
Director, Corporate Regulatory
and Clinical Affairs

(Draft) Medtronic comments on “Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme” as released for comment on February 8, 2000 Docket Number Docket No. 00D-0053

General

The draft guidance is a distinct improvement over the first proposal. The one element that is still missing is consideration of the uncontrolled processes that are inherent in a reused SUD: the initial use process and the recovery process.

As was explained in earlier Medtronic comments, process control is essential for safety and effectiveness. To the extent processes are not controlled, safety and effectiveness is not assured. To the extent safety and effectiveness is not assured, there is inherent increased risk.

Final testing/inspection of the product is not sufficient to assure safety and effectiveness. If it were sufficient, final product testing would obviate the need for compliance with or enforcement of the Quality System Regulation for manufacturers of medical devices.

Another concern is that the risk associated with a device may be design-specific while the scheme treats them by generic category.

Specific comments are provided below.

Specific comments

Introduction, (second paragraph)

Comment:

While device type may provide some general approach to risk, each product's specific design needs to be taken into account if risk is to be properly addressed. For example, minor physical differences in a catheter may make the cleaning process much more difficult. This is discussed in more detail below.

Flowchart 1: Evaluating the Risk of Infection

Question 3: Does the SUD include features that could impede thorough cleaning and adequate sterilization/disinfection?

Comment:

This question shows the need to consider the specific model of a SUD when assessing risk. Where disassembly and reassembly are necessary during reprocessing, latent damage may be introduced that may not show up under final test. The original OEM assembly process includes training and work instructions specific to the model. OEM assembly also assumes single use. Reprocessing or, more appropriately, remanufacturing (with the inclusion of disassembly) the SUD into a reusable that will be remanufactured yet again could well require much more exacting controls than were required to make the original SUD.

The question should be reworded, inserting the phrase "specific model" before "SUD".

Question 4: Does a reusable device exist that has an equivalent design and the same intended use as the SUD?

Comment:

A reusable device cannot be considered equivalent in design and intended use to a SUD. A thoughtful view of design includes evaluations including risk analysis based in significant part on intended use. These evaluations have a significant impact on the content of the labeling as well.

Even as elements of a decision matrix to set enforcement priorities, questions should not encourage superficial, indiscriminate ways of thinking about the subject. It is strongly recommended that this question be deleted from the flowchart.

Question 5: Are there recognized consensus performance standards, performance tests recommended by the OEM, or a CDRH guidance document that may be used to determine if the SUD has been adequately cleaned and sterilized/disinfected?

Comment:

While standards can be resources beyond their intended application, this must be carefully justified. Device standards are written based on devices being used as intended including single use or multiple use, as the case may be. The same observations would apply to OEM tests and CDRH guidance as well. Regardless of whether or not the standard specifies single or multiple use, the experience base must be taken into account. It is also important to note that standards are written and applied with the understanding that they will be used in

the context of processes controlled under quality systems. The FDA requires an OEM to have controlled processes as well as meeting finished device criteria.

These observations apply to other flowchart questions with similar content

Flowchart 2: Risk of Inadequate Performance (Appendix 1)

Question 3: Does the SUD contain any materials, coatings, or components that may be damaged or altered by a single use or by reprocessing and/or resterilization/disinfection in such a way that the performance of the device may be adversely affected?

Comment:

The question appropriately acknowledges that degradation can occur with a single use. Handling subsequent to use in the recovery process, may also cause degradation and should be added to the question. Use and recovery are both uncontrolled processes and, as such, increase risk as described above in the general comments. This is another example of the need to consider devices model-by-model rather than by general category.

(Draft) Medtronic comments on: “Guidance for Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals”, released for comments February 8, 2000, Docket No. 00D-0053

General

The draft guidance clarifies that third party reprocessors are subject to the same regulatory requirements as other manufacturers. Consequently, Medtronic agrees that premarket notification and premarket approval requirements should be enforced where applicable on reprocessed single use devices, (SUDs), Medtronic further agrees that this premarket regulation should be phased in using an appropriate review prioritization scheme.

Medtronic is concerned that the FDA's current enforcement of requirements applicable to manufacturers against third party reprocessors of SUDs may be construed as a history of enforcement. The outline of the requirements of the Act that is provided in the draft guidance would not be necessary for the third party reprocessors if there were a history of enforcement. More specific concerns regarding enforcement are given below under specific comments

Specific Comments

D. Why is FDA phasing in the enforcement of regulatory requirements for SUD reprocessors?

The first paragraph in this section contains the assertion that, excepting premarket requirements, “...FDA currently enforces all other requirements applicable to manufacturers (such as registration, adverse event reporting, and quality systems regulations) against third party reprocessors.”

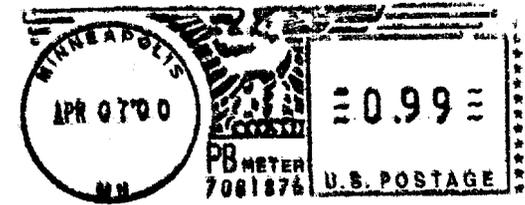
In a recent talk paper, the FDA cites a list of several violations by a third party reprocessor. As the report does not indicate any progress toward correcting violations from earlier inspections a reasonable conclusion is that there were none. This can be a particular problem because multiple reuse requires multiple reprocessing events, some of which will have taken place when processes were not in control. Taken along with the uncontrolled processes of use and recovery, this is cause for alarm considering the importance of process control for the OEM, fortified by QSR inspections by the FDA.

Proper labeling is also one of the general controls that should not be deferred to the time when premarket notification/approval is enforced. Labeling of third party reprocessed SUDs requires addressing substantive issues particular to the situation of offering a device for reuse that has been labeled for a single use.

By offering the reprocessed SUD for reuse, the third party reprocessor is making an important claim: that the reprocessed SUD is reusable. Notwithstanding this questionable assertion, the reprocessor should be required to label the device appropriately including information on how the device is to be prepared for yet another reuse. Labeling should also clearly express the fact that the device degrades with multiple uses. Labeling with the reprocessed SUDs should make this clear and provide specific warnings and precautions to take in the event of these known failures occurring during use.

There is also the need to provide adequate instructions for use, indications, contraindications, warnings and precautions. Both packaging labeling and labels on the device itself must be addressed. Because the third party reprocessor is asserting reusability in contradiction to the single use intent of the OEM, the full responsibility for the device must fall on the third party reprocessor. This requires that the device itself bear labeling that unambiguously identifies the third party reprocessor as the source of the device

The FDA should not wait until premarket notification/approval requirements are enforced to review labeling from third party reprocessors. The issues noted above could well be only a small part of the labeling deficiencies and probably not the most serious. It is worth noting in passing that the third party reprocessor is effectively ignoring the original single-use label. This attitude toward labeling warrants a regulatory review of reprocessor labeling without waiting for implementation of premarket requirements.



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