



April 6, 2000

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Docket No. 00D-0053
Dockets Management Branch
Division of Management Systems and Policy
Office of Human Resources and Management Services
Food and Drug Administration
5630 Fishers Lane, (HFA-305)
Room 1061
Rockville, MD
20852
USA

**Re: Enforcement Priorities for Single Use Devices Reprocessed by Third Parties and Hospitals
Reprocessing and Reuse of Single Use Devices: Risk Prioritization Scheme**

Dear Sir/Madam:

Medical Devices Canada (MEDEC), a national voluntary trade association for the medical devices industry in Canada, hereby submits the following comments regarding the above referenced FDA draft guidance documents. Several Canadian companies that are members of our association manufacture single use devices and sell into the United States. The reuse of single use devices is a very serious concern for our members and therefore we wish to avail ourselves of the opportunity to comment on the FDA proposed strategy.

In general, MEDEC does not condone the reuse of single use medical devices. Single use devices that are reused contrary to labelled indications pose a certain amount of risk and therefore the practise should be discouraged at the institutional level. Nevertheless, economic constraints compel institutions to reuse a device contrary to labelled indications and therefore a strategy that seeks to reduce the risks associated with this practise is desirable.

Ultimately, the decision to reuse should be based on the ability of the reprocessor to validate the procedure to the same standards as the original manufacturer (OEM). Regulatory requirements should be no less stringent for the reprocessor as they are for the OEM. The ultimate objective should be to demonstrate that the process results in a product that is as safe and effective as originally manufactured.

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Regulatory requirements in the US impose a burden of responsibility on the manufacturer to demonstrate the safety and effectiveness of a device for its intended use. Reprocessing a single use device and offering that device for subsequent reuse is tantamount to altering the indications for use. The burden of responsibility to demonstrate the safety and effectiveness of this new indication for use should apply equally to the reprocessor. Therefore, MEDEC supports in principle, the FDA enforcement priority which seeks to apply the law equally to reprocessors of single use devices.

Furthermore, MEDEC supports in principle the FDA risk categorization scheme for single use devices. We do however submit the following specific comments regarding the Review Prioritization Scheme document.

In both flowchart 1 and flowchart 2, questions 2 and 1 reference post market information. These questions are appropriate provided there is information available on incidents involving reused single use devices. Generally, industry experience in Canada has shown there is little postmarket information available since most hospitals are unlikely to report an incident involving a single use medical device. If this is true in the United States, then this paucity of information would lead one always to answer no to these questions. This has the effect of reducing the probability that the device may be classed as high risk.

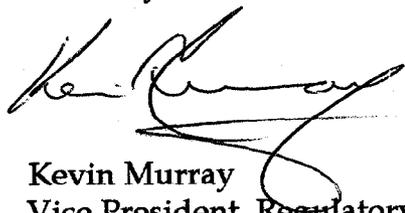
In flowchart 1, question 3, adequate sterilization/disinfection is a criteria in determining whether to proceed with reuse. Manufacturers (OEM) are required to demonstrate a reasonable sterility assurance level (in most cases 10^{-6}) in order to satisfy regulatory requirements. A reprocessor should be subject to the same requirements and therefore this question should be more prescriptive in terms of the expectations for adequate sterilization/disinfection.

In flowchart 1, question 4, an assumption is made that similarity of design to an existing reusable device constitutes a low risk. It is our understanding that in the US, substantially equivalent devices may be granted premarket clearance based on an equivalent indication for use to a predicate device. In the case of a single use device, the indication for use (one time) is not equivalent to a reusable version. Therefore, this question would assign a low risk to a device with a different intended use that would not normally be considered low risk if the OEM were to apply for premarket clearance based on substantial equivalency.

In flowchart 2, question 2b asks if visual inspection can determine if performance has been affected. We suggest it is inappropriate to make a determination of performance based on visual inspection alone. Manufacturers must provide to a regulator, evidence of performance based on scientific data and would not likely satisfy the regulator's requirements based on visual inspection alone. Furthermore, physical changes to the device following reprocessing and reuse are not always evident to the naked eye. Significant changes which could lead to serious deterioration in the performance of the device may only be visible under high magnification.

We appreciate this opportunity for comment and trust the above will be considered by the FDA in the final ruling on this issue.

Sincerely,

A handwritten signature in black ink, appearing to read "Kevin Murray". The signature is fluid and cursive, with a large loop at the end.

Kevin Murray
Vice President, Regulatory Affairs

Swift

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