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Dockets Management Branch
Division of Management Systems & Policy
Office of Human Resources & Management Services
Food & Drug Administration
5603 Fishers Lane, Room 1061 (HFA-305)
Rockville, MD 20852

Docket Number 99N-4491

Re : Proposed Strategy on Reuse of Single-Use Devices

As a manufacturer of medical devices for more than 25 years we would like to thank the staff at the FDA for examining the difficult issue of the reuse of single-use devices and comment on your proposed strategy.

Adept-Med manufactures a Class 1, single use, sterile medical device, exempt from 510(k) requirements. Independent laboratory studies confirm that positive sterility of our device can only be achieved with gamma irradiation. The material will deteriorate beyond use with steam and fails to achieve positive sterilization with other conventional methods of sterilization, i.e. etc etc. We therefore feel that your enforcement of regulations to protect patients from the reuse of our device and devices similar in nature to ours is essential to patient safety.

We would suggest that the method of categorization currently being considered, i.e. Class 1, exempt, being the least burdensome, "Low-Risk", would not be appropriate when examining reuse / sterilization issues, as is clearly evidenced by our own Class 1, exempt device.

Many Class 1, exempt devices are surgically invasive devices. They have been placed in a Class 1 category due to their long standing in the surgical arena without adverse events. This does not change the fact that they are in contact with blood and tissue and can carry a heavy bioburden load after use.

Our device in particular has small holes that are a necessity of the molding process. These holes can and do allow tissue and blood products to travel well within the interior of the device. I have spoken with surgeons, OR nurses, OR technicians, central supply workers and others in the surgical field and know that this migration of fluid / tissue into the device is not readily apparent to these people.

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One need only read down a list of Class 1 devices to realize that they should not be in a category of least burdensome, "Low-Risk", or exempt when it comes to stringent standards for sterilization and reuse :

- Catheters : Suction, Tracheobronchial, Nasal, Urological, Introduction / drainage ;
- Manual gastroenterology urology surgical instruments and accessories ;
- Ribdam ;
- Interlocking urethral sound ;
- Organ bags ;
- Nonabsorbable gauze for internal use ;
- Manual surgical instruments for general use ;

to name only a few.

I have used the FDA's Draft Guidance document to evaluate our own device. By Class the "Inherent Risk" is 0. As previously stated ; surgical / hospital staff admittedly do not recognize that there are "Inaccessible Parts" in our device therefore would rate our device to be a Grade 0 or 1 "Risk of Infection" and the "Risk of Inadequate Performance", is Grade 0. By your proposed system we have a device that is classified as Low Risk, when in fact, this device will not be sterile (as evidenced by repeated independent laboratory studies) if reprocessed and **will** pose a serious health hazard to the next surgical patient if reused.

We would suggest the European Union method of classifying devices, coupled with information supplied by the OEM is more appropriate to the task at hand. Invasive devices having a higher level of risk assigned versus non-invasive devices ; devices coming in contact with blood, body fluids and tissue having a higher level of risk. Solid scientific evidence regarding the ability of a device to be reprocessed / resterilized must be a factor if patients are to be protected. If an OEM has solid, independent, scientific evidence that a device will not be sterile if reprocessed and reused then that evidence must be considered and the device should never be reprocessed / reused.

Further, third party reprocessors should bear the same burden and responsibility as OEM's when enforcing the CFR's, including 510(k), QSR requirements, inspection and MDR. In the October 1999 issue of Medical Device and Diagnostic Industry, Mr. William Stoermer, Executive VP of Alliance Medical Corp. wrote an editorial in which he indicates that third party reprocessors hold patient safety above all. He states that his company and third party reprocessors in general adhere stringently to GMP regulations and CFR requirements. Yet when his company was held to the same standard as all OEM's in a November 1999 FDA inspection Alliance Medical Corp. was found to have serious violations involving good manufacturing practices, quality control, training, corrective / preventative action and failure to maintain device history records to ensure that the devices were reprocessed properly (FDA Talk Paper, December 27, 1999). Alliance Medical Corp. inspection results are a clear indication that third party reprocessors require inspection and enforcement equal to OEM's if the public is to be protected.

We encourage a working definition of "Single-Use", "Reuse", "Reprocessing" etc. These definitions should include language that indicates if a device can or can't be safely reprocessed / reused based on sound scientific evidence and standards.

Thank you for considering our comments on this difficult issue and examining this area of public safety.

Sincerely,

Chris Quigley
Executive Vice President