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**Docket No. 99N-4491
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, MD 20852**

RE: REPROCESSING SINGLE USE DEVICES - PUBLIC COMMENT

COMMENT #1 GENERAL

The FDA has changed its stance on reprocessed SUDs from not requiring premarket 510(k)s and PMAs to requiring them, and is aggressively publishing its position on the new requirements to the industry, including hospitals (potential customers). Reprocessors should be able to openly advertise when it has obtained an FDA clearance/approval for a given device.

Please consider modifying existing advertising regulations in regards to reprocessed SUDs.

**COMMENT #2 PROPOSED STRATEGY ON REUSE OF SUDS
RISK CATEGORIZATION SCHEME**

The release of the FDA's PROPOSED STRATEGY ON REUSE OF SUDS and RISK CATEGORIZATION SCHEME are not comprehensive enough for adequate comment... for example: 1) the time requirements must be more clearly identified... i.e.: does six months mean ODE must have the submission cleared/approved or that submitter must have the 510(k) or IDE submitted for ODE's review, 2) the list of reprocessable items is incomplete in the PROPOSED STRATEGY ON REUSE, 3) the opened but not used items are left without comment.

Please consider providing the industry the opportunity to comment again on the updated version of each of these documents.

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COMMENT #3 PROPOSED STRATEGY ON REUSE OF SUDS

In the PROPOSED STRATEGY ON REUSE OF SUDS, diagnostic electrophysiology catheters are listed as Class II. In the RISK CATEGORIZATION SCHEME, ablation catheters are listed as Class III. Please add ablation catheters as a different device from diagnostic electrophysiology catheters.

Please add disposable Sequential Compression Sleeves, Femoral Compression Devices, Bone Shavers, Keratome Blades and Blood Pressure Cuffs to the list.

**COMMENT #4 PROPOSED STRATEGY ON REUSE OF SUDS
RISK CATEGORIZATION SCHEME**

In the PROPOSED STRATEGY ON REUSE OF SUDS under "High Risk Reprocessed SUDs" the FDA states "... products in this category should be removed from the market within a short time frame if they have not complied with applicable premarket requirements. ...including premarket requirements, within six months..."

In using the above verbiage, in conjunction with the Risk Categorization Scheme, it is not clear if it is the FDA's intention to require IDE/PMAs for "High Risk" devices, regardless of the inherent generic classification (Class I, II, III) the device is under for single use?

We ask the FDA to clearly state that the type of premarket requirement depends on the devices inherent generic classification (Class I, II and III), and the urgency of the premarket requirement is dictated by the device risk, identified in the Risk Categorization Scheme.

**COMMENT #5 PROPOSED STRATEGY ON REUSE OF SUDS
RISK CATEGORIZATION SCHEME**

Assumption: FDA requires IDE/PMA on Class III, High Risk devices only.

Over the last several months, the FDA has made many requests for additional data on the safety of reuse. In the RISK CATEGORIZATION SCHEME, the FDA showed ablation catheters as Class III, high risk devices which implies IDEs/PMAs. Yet there currently exists a significant amount of published data on the safety of reusing ablation catheters.

Of all the SUDs reprocessed in the United States (excluding dialyzers) EP diagnostic and ablation catheters have been reprocessed more than any other device. Published studies and protocols on reprocessing catheters are available from several sources. Most third party reprocessors today use the same core reprocessing protocol for diagnostic and ablation catheters but additional testing is performed on ablation catheters for RF energy output, temperature sensibility and steerability. From the view of the reprocessors, the different premarket requirements are unjustified.

We ask the FDA to consider differentiating premarket requirements between Class III, High Risk reprocessed SUDs that have little or no published safety data (such as reprocessed PTCA catheters) verse Class III, High Risk SUDs that have plenty of published safety studies (reprocessed cardiac ablation catheters).

COMMENT #5 RISK CATEGORIZATION SCHEME

Performance Flowchart #2 Question Number 3. Can the performance of the device be evaluated with only visual inspection? No (Grade 2), Yes (Grade 1).

None of the invasive or non invasive medical devices reprocessed by AMI can be evaluated with only visual inspection. Reprocessors pride themselves in finding new and innovative ways to test functionality.

We ask the FDA to consider changing the question, from "Can the performance of the device be evaluated with only visual inspection?" to "Can the performance of the device be clearly evaluated?"

COMMENT #6 RISK CATEGORIZATION SCHEME

Infection Flowchart Question Number 3. Does post market information suggest that using the reprocessed SUD may present an increased risk of infection when compared to the use of an SUD that has not been reprocessed and/or reused?

All used, critical SUDs have an increased risk of infection because of the simple fact they are used.

We ask the FDA to consider removing Question #3. If the device is critical, and difficult to clean, disinfect or sterilize - Grade 2. If not, does the SUD contain any microbial materials...



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