

GUIDANT

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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, MD 20852

Subject: Comments on the "FDA's Proposed Strategy on
Reuse of Single-Use Devices
Docket No. 99N-4491

Dear Sir or Madam:

Enclosed are the comments from Guidant Vascular Intervention concerning "FDA's Proposed Strategy on Reuse of Single-Use Devices".

Guidant Corporation develops and manufactures medical devices to provide physicians and patients with leading edge technologies for improved patient care and clinical outcomes. Guidant's primary concern in developing innovative products is patient safety. Throughout the product development process, Guidant performs extensive and rigorous testing and validations to ensure our products perform both safely and effectively for their labeled intended use. This testing directly supports whether the product is labeled for single or for multiple-use. Patient safety is paramount and ensuring that Guidant devices are used as labeled is in the best interest of both our patients and physician customers in supporting positive clinical outcomes.

Guidant products labeled as single-use only devices have been tested and validated to support this claim. These devices have not been validated after being subjected to cleaning and resterilization processes, and as such Guidant cannot ensure that the product will continue to be safe and effective for multiple use. When validating a device such as a balloon dilatation catheter for reuse, the following variables should be considered at a minimum, including the clinical procedure, the decontamination process, the resterilization process and the actual device performance. Additionally, considerations to ensure and/or prove the safety of the device for re-use will include variables such as the number of balloon inflations performed, balloon pressures, duration of balloon inflation and patient anatomy, specifically vessel tortuosity, lesion classification and degree of calcification. The cumulative effects of stress in re-use will vary with clinical scenarios and may be difficult to simulate in an experimental situation. Decontamination processes vary in types of cleaning agents, temperatures employed, duration of the cleaning cycle, and the effects of the cleaning process on material degradation and device coatings. A dilatation device that was not adequately cleaned could have reduced functional performance that could jeopardize patient safety. For example, residual contrast in the inflation lumen of a device could result in an increase in the balloon deflation time.

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There is also an increase in the risk of successfully decontaminating certain polymeric materials in devices with complex geometry and small lumens such as balloon catheters. In the case of improper and/or inadequate cleaning of these devices, there is the potential to prevent adequate penetration of the subsequent sterilant, thus rendering the sterilization ineffective. Resterilization processes need to address material compatibilities with the sterilization method, the operating parameters of the resterilization processes and how these affect product performance. The physical and chemical effects of both the cleaning and sterilization processes associated with reprocessing have the potential to cause the device to not perform as intended. The increasing use of advanced materials with high stress and heat sensitive properties as well as the use of product enhancing coatings can be affected by the cleaning and sterilization methods of the reprocessing process. Reprocessing also eliminates the benefit of the product attribute associated with the coating. Additionally, "wiping down" of devices as part of many resterilization processes will add unknown stresses to sensitive catheter components and may cause damage that will not be noticed until the product is reused.

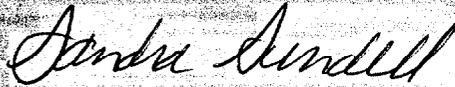
Evaluating all of the factors discussed above in the design of a validation for balloon reuse provides a challenge since one cannot predict all variables each reused balloon will encounter. There is also market pressure to develop new materials with enhanced initial performance, but these materials may have poor reuse characteristics. This in addition to the cumulative effects of clinical usage, cleaning and resterilization would be difficult to simulate in an adequate product validation.

The reuse issue is one concerning patient safety and product performance integrity not one of economics. The cost of balloon angioplasty catheters, for example, depicts how prices have dropped significantly in the past few years due not to excessive pressure from resterilization, but due to increased competition. Competition continues to drive enhanced performance of devices and lower prices. Manufacturers, customers and patients are interested in performance and clinical outcomes. Potential costs of reuse include the costs associated with increased risks to patients of clinical complications, increased insurance costs, longer hospital stays, and the costs of potential litigation. Setting up a reuse system also has inherent cost to the hospital and the health care system associated with saving the devices after a procedure, preliminary cleaning, documenting, moving, and device tracking. Patient notification is also of paramount interest. Patients have the right to know whether a reuse SUD is being used in their procedure which can best be addressed through the patient informed consent process. How is it equitably determined which patients get new devices and which patients get used devices? What is the increased risk of infection due to inadequate or improper cleaning, inadequate sterilization or increased patient exposure to bacterial endotoxins? In the

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event of an issue with a resterilized product, how is the responsibility for the device failure apportioned? Product quality and performance, patient safety and enhanced clinical outcomes should be the abiding force in enforcing existing 510(k) premarket notifications and PMA premarket approval requirements.

Respectfully Submitted,



Sandra Sundell
Senior Regulatory Affairs Coordinator

Enc.

1. Reconsider the agency's current policy on establishments that reprocess SUDs.

Guidant feels that it is appropriate for FDA to exercise its regulatory authority over all entities classified by the FDC Act § 510 (a) (1) as meeting the definition of a manufacturer, including reprocessors. While commercial reprocessors are deemed manufacturers for the purposes of device listing, registration, QSR, Labeling and MDR reporting, FDA's decision to exercise regulatory discretion and exclude reprocessors from the definition of a manufacturer for purposes of premarket notification and/or premarket approval regulation is in conflict with the existing regulation. Equitable enforcement by the FDA is in the patient's best interest. In order to ensure the safety and effectiveness of medical devices, manufacturers assess the intended use of the device, the technological requirements including design and materials as well as sterilization and sterility requirements. Based on the substantive pre-clinical testing, the single use only label is affixed to the medical device label and represents with reasonable assurance that the device will be safe and effective.

Reprocessing of a single use device changes the intended use of the device from single to multiple use. This change in intended use can significantly affect the safety or effectiveness of the device. If Guidant were to label its devices for multiple use, as with the single use label, Guidant would have to re-validate to demonstrate the safety and effectiveness of the device after multiple uses. Reprocessors along with OEMs must be held to the same regulatory requirements and should be required to demonstrate to FDA that after reuse, the devices continue to be both safe and effective for their intended use. FDA needs to enforce its own regulations and fulfill its responsibility under the FDC Act to protect the public health through universal enforcement of the existing 510(k) and premarket regulations.

2. Explore the development of a device categorization system based on the level of risk presented by reprocessing and reusing SUDs and an enforcement strategy based on the level of risk.

FDA's current regulations include a risk based categorization scheme. If FDA intends to explore a new risk based categorization system for reprocessing medical devices labeled for single use only, this categorization needs to be based on data supporting the appropriate categorization of the device. In addition to the factors mentioned in FDA's proposed strategy on reuse of single use devices, FDA needs to consider the product performance characteristics, device design, materials, coatings, compatibility with multiple sterilization methods, multiple sterilization cycles and the compatibility of materials and designs with various cleaning methods. All of these factors need to be addressed and supported with scientific data.

In FDA's proposed three tiered categorization scheme a high risk category should include all current Class II and Class III devices currently subject to the 510(k)

and PMA requirements. Data should be submitted and reviewed by FDA to ensure the safety and effectiveness of these devices when subjected to reprocessing and to support a change in the device's intended use from single to multiple use. FDA's proposed classification scheme should also address the continuing development of complex medical products designed to meet physician demands. For example, PTCA catheters and guide wires are technological devices that become increasingly more complex to meet the demand for innovative, high performance devices.

The low risk category should include only Class I exempt devices.

The moderate risk category should include all Class I non-exempt devices. Consistent with current regulation, FDA should require scientific data for review to ensure the safety and effectiveness of these devices when subjected to reprocessing and to support a change in the device's intended use from single to multiple use.

What type of post market data should reprocessors collect during the proposed two year enforcement period?

The proposed guidance on SUDs if implemented, needs to ensure reprocessed, resterilized and reused products are safe, of high quality and perform to product specifications. Premarket notification requirements and premarket approval regulations should be the primary enforcement action rather than relying on post-market data. Reprocessors should be responsible for complying with existing regulation of 510(k) and PMA requirements including existing labeling requirements as applied to manufacturers of medical devices.

3. Solicit comments on the FDA's draft list of "Frequently Reprocessed SUDs".

Guidant ACS believes that Cardiac Catheters and guidewires (Class II and III, 510(k) and PMA) and Balloon Angioplasty (PTCA) Catheters (Class II, PMA) included in FDA's proposed list of "frequently reprocessed SUDs" should be classified as "high risk" devices. Manufacturers of these types of medical devices are currently held to 510(k) and PMA requirements. All entities classified by the FDC Act § 510 (a) (1) as manufacturers should be held to these requirements including commercial reprocessors. Valid scientific data should be submitted to FDA to support changes in intended use including a change from single use to multiple use. Existing labeling requirements as applied to manufacturers of medical devices should also be applied and enforced for all manufacturers including commercial reprocessors. All devices reprocessed by a commercial reprocessor and resold should be labeled with the commercial reprocessor's labeling and identified as reprocessed and reused devices.

4. Consider requesting OEMs to provide information on their labels about risks associated with reuse of SUDs.

Guidant ACS believes the safety and performance characteristics of the reuse of devices labeled for "single use only" should be the responsibility of the entity that is responsible for the reprocessing of the device. Premarket review and 510(k) notification should be required prior to the reprocessing of the device. This should include adequate testing after the cleaning and sterilization processes and after each number of times the reprocessor claims the device can be reprocessed. Additionally, the labeling of the reprocessed devices should indicate that the device has been reprocessed and reused and reflect the name of the commercial reprocessor. All future product liability will be the responsibility of the commercial reprocessor. The OEM of the device should not be responsible for modifying an existing SUDs product labeling to accommodate the practices of a commercial reprocessor that are in direct contrast to the original manufacturer's intended use of the device. For reasons stated previously, OEMs cannot anticipate all of the risks associated with reprocessing as the risks will vary with the type of product usage, the type of sterilization, the number of resterilizations, etc.

5. Examine the need to create working definitions for the terms "single-use device", "reuse", "reprocessing", and "resterilization".

Guidant ACS believes that definitions should be created for the terms "single-use device", "reuse", "reprocessing", and "resterilization". Additionally, definition (2) under A - "Single-use device" is currently covered under definition C - "Reprocessing" and should be removed from definition A.

6. Explore how recognized consensus standards can be applied to reprocessing SUDs (e.g., to verify and validate cleaning, disinfection and/or sterilization of SUDs) and explore the development of additional consensus standards to address the safety, effectiveness and performance of reprocessed SUDs.

Premarket notification requirements and premarket approval regulations should be required for all manufacturers including reprocessors. Under existing regulation where appropriate, a manufacturer may declare conformity to a recognized standard to ensure that the device to be marketed remains safe and effective for its intended use. However, existing regulation does not recognize conformance to recognized standards when the intent is to change the intended use of the device, including changing from a single use to multiple use indication. This change in intended use could significantly affect the safety or effectiveness of the device. The device would have to be re-validated to reflect the safety and effectiveness after multiple uses. Reprocessors along with OEMs must be held to the same regulatory requirements and should be required to demonstrate to FDA that the

reuse or change from single to multiple use of these devices are both safe and effective for their new intended use.

7. Consider developing a research program on reuse of SUDs and explore avenues to publish and disseminate research and other information on reuse.

Scientific data needs to be accumulated and reviewed by FDA prior to the categorization of medical devices into FDA's proposed risk based categorization scheme. Scientific data needs to be available to determine the risks associated with the specific device and the effects, if any, of the process of reprocessing on the safety and effectiveness of medical devices. The data need to be available prior to the determination of the medical device categorization into an appropriate risk level. Additionally, the data to support the proper classification of devices into risk-based categories needs to be available prior to the implementation of this proposal and prior to the implementation of the adoption of consensus and performance standards.

The agency also needs to consider the historical risks associated with reused devices including patient safety and increased risk of infection, sterilization method compatibility and sterilization validation methods, contamination due to bacterial endotoxins and the difficulty of tracing patient infections with long incubation periods back to the source of infection.

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