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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Subject: Comments on FDA's Draft Guidance, "Reprocessing and Reuse of Single-Use Devices Risk Categorization Scheme"  
Docket No. 99N-4491

Dear Sir or Madam:

Enclosed are the comments from Guidant Vascular Intervention concerning FDA's Draft Guidance, "Reprocessing and Reuse of Single-Use Devices Risk Categorization Scheme".

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. Through the product development process, Guidant ensures products perform both safely and effectively for their labeled intended use through extensive and rigorous product testing and validation. These data support 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. Validating a device for reuse involves many variables and combinations thereof that cannot be adequately and safely addressed in FDA's proposed draft guidance document. Evaluating all of these factors provides a challenge in predicting all variables each reused device will encounter. Also of consideration is the continual market pressure to develop new materials with enhanced initial performance, but these materials may have poor reuse characteristics. Evaluating the additional patient risks of potential infection and device performance including the cumulative effects of clinical usage, patient anatomy, cleaning and resterilization would be a challenge to simulate in an adequate product validation and difficult to thoroughly assess through the use of both risk evaluation flowcharts included in this draft proposal.

The evaluation of risk associated with device reuse and reprocessing needs to be based on the accumulation and analysis of scientific data. These data need to be accumulated and

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reviewed by FDA prior to the categorization of medical devices into FDA's proposed risk based categorization scheme. Scientific data need 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. These data need to be available prior to the determination of the medical device categorization into an appropriate risk level. Additionally, these data to support the proper classification of devices into risk-based categories need to be available prior to the implementation of this draft guidance document.

Respectfully Submitted,

A handwritten signature in cursive script that reads "Sandra Sundell".

Sandra Sundell  
Senior Regulatory Affairs Coordinator

Enc.

### **Comments on Introduction and General Approach**

The Food and Drug Administration's implementation of a new Risk Categorization Scheme (RCS) as outlined in the current draft guidance document, "Reprocessing and Reuse of Single-use Devices Risk Categorization Scheme, is in direct contrast to the responsibilities outlined for FDA in the Food Drug & Cosmetic Act (FD&C Act). Reuse of single-use only devices (SUD) consists of cleaning, disinfecting and resterilizing and reusing medical devices, originally labeled by the original equipment manufacturer (OEM) for single-use only. Medical devices are labeled as single-use only devices through extensive product development processes including extensive and rigorous product testing and validations to ensure these products perform both safely and effectively for their labeled intended use. These data directly support whether the product is labeled for single or for multiple-use, determining the intended use of the device.

Reuse of devices labeled for single-use only raises concerns regarding patient safety, informed consent and equitable regulation of reuse under the FD&C Act. Guidant Agrees with FDA's statement in the guidance document that, "The RCS establishes a way to evaluate the level of risk associated with the reuse of a SUD. The approach assumes that reprocessing or reuse adds to the inherent risk of the SUD." FDA's draft RCS may establish "a way" to evaluate the increased level of risk but is not comprehensive enough to ensure adequate patient safety, patient informed consent and that the reused products will continue to perform as intended by the OEM. Guidant agrees that Reuse not only adds to the inherent risk of the SUD, but also that reuse without following existing premarket notification and premarket approval requirements is in direct violation of the FD&C Act.

FDA states in the Introduction section of the guidance document the following paragraph,

"The FDA's Center for Devices and Radiological Health bases its regulation of medical devices on the risk a device presents to patient health. FDA's premarket review of a product labeled for single use does not ordinarily address whether any attempt to reprocess and /or reuse such a device would present a risk to public health. Despite labeling for single use, many devices may be reprocessed by hospitals, clinics or reproprocessors without adequate evaluation of the possible increased risk to the patient during reuse of the device."

Guidant agrees with the statement that FDA CDRH bases its regulation of medical devices on the basis of risk. FDA's current regulations include a risk based categorization scheme. The FDA proposed draft guidance outlines a new risk based categorization system for reprocessing medical devices labeled for single-use only, but this system is based on working through a flowchart and answering questions, and in essence is based upon individual interpretation, not based on data. Reprocessed device

data are needed for every device subjected to this new RCS to support the appropriate categorization of these devices. Other product performance characteristics outlined in the flowchart are subjective including device design, materials, design changes and modifications, 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, not individual interpretation.

“FDA’s premarket review of a product labeled for single use does not ordinarily address whether any attempt to reprocess and /or reuse such a device would present a risk to public health.”

FDA does not ordinarily address risks associated with potential reprocessing of SUDs because as stated in the FD&C Act §513(i)(1)(E)(i) their determination is limited to the proposed labeling submitted in a report for the device under premarket notification regulations. FDA’s regulatory authority over the intended use of a device is limited to the sponsor’s proposed labeling. FDA should follow its charter outlined in the FD&C Act and not continue to promote off label practices of reuse and reprocessing of SUDs. FDA needs to enforce its own regulations and fulfill its responsibility under the FD&C Act to protect the public health through universal enforcement of the existing 510(k) and premarket approval regulations.

“Despite labeling for single use, many devices may be reprocessed by hospitals, clinics or reprocessors without adequate evaluation of the possible increased risk to the patient during reuse of the device.”

FDA needs to exercise its regulatory authority over all entities classified by the FD&C 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. 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.

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 for its labeled intended use.

### **Flow chart 1 – Evaluating the risk of infection**

FDA's flow chart outlining a method for evaluating the risk of infection when reprocessing medical devices labeled for single-use only is inadequate for ensuring patient safety. This system is based on working through the flowchart and answering questions, in essence is entirely based upon subjective evaluation, not based on data. The risk associated with an invasive medical device not being sterile is an unacceptable risk to patient safety. With the current lack of post-market data available, how can one adequately assess the increased risk of infection due to inadequate or improper cleaning, inadequate sterilization or increased patient exposure to bacterial endotoxins? There is also an increase in the risk of successfully decontaminating certain polymeric materials in devices with complex geometry and small lumens. 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.

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.

### **Flowchart 2 – Evaluating the Risk of Performance Change**

FDA's flow chart outlining a method for evaluating the risk of product performance when reprocessing medical devices labeled for single-use only is also inadequate to ensure patient safety. This system is based on working through the flowchart and answering questions, in essence is also based upon subjective evaluation, not based on data.

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.

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.

For reasons stated previously, OEMs even with the use of these draft flowcharts cannot anticipate all of the risks associated with reprocessing as the risks will vary with the type of product usage, patient anatomy, the type of sterilization, the number of resterilizations, etc. If OEMs cannot predict these additional risks, how are reprocessors supposed to ensure the continued safety of these devices?

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 draft guidance document.

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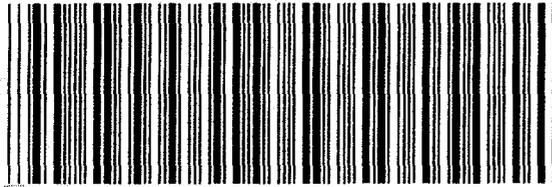
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