HOGAN & HARTSON

L.L.P

1423 '03 AUG -4 P2:13

JONATHAN S. KAHAN
PARTNER
(202) 637-5794
JSKAHAN@HHLAW.COM

COLUMBIA SQUARE
555 THIRTEENTH STREET, NW
WASHINGTON, DC 20004-1109
TEL (202) 637-5600
FAX (202) 637-5910
WWW.HHLAW.COM

August 4, 2003

Docket Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Comment on Termination of Exemptions from Premarket Notification (Docket No. 03N-0161)

To Whom It May Concern:

On behalf of Guidant Corporation (the "Company"), this letter requests that the Food and Drug Administration ("FDA" or the "Agency") update the List of Critical Reprocessed Single Use Devices Previously Exempt From Premarket Notification Requirement That Will Now Require 510(k)s With Validation Data (the "List") published in the Federal Register on April 30, 2003. 68 Fed. Reg. 23,139. We request that the List be revised to include heart stabilizer devices classified under 21 C.F.R. § 870.4500 and assigned the product code "MWS." FDA should include heart stabilizer devices on the List because of the potential high risk of infection and potential high risk of inadequate performance after reprocessing.

I. FACTUAL BACKGROUND

A. Device Description

FDA has classified heart stabilizers as "cardiovascular surgical instruments" under 21 C.F.R. § 870.4500. They are assigned the product code "MWS."

Heart stabilizer devices use pressure or suction as their principal mode of operation to stabilize, move, lift, and position the heart while maintaining hemodynamic stability during cardiovascular surgery. Generally, these devices consist of a suction cup or stabilizer foot, tubing for connection to a vacuum source,

03N-0161 C 2

a rigid or flexible arm that may be mounted on a retractor, and an adjustable knob for manipulation of the arm to move, lift, and position the heart. These components are exposed to blood and body tissue during use and incorporate interlocking parts, narrow lumens, and small crevasses that are likely to trap blood and body tissue during normal use. These components also consist of materials that may be damaged or altered by reprocessing in such a way that performance of the device may be adversely affected.

Although the heart stabilizers manufactured by the Company are labeled and sold as single use devices, Guidant has learned that several companies ("Reprocessors") are sterilizing these products after use and reselling them as reprocessed single use devices ("RSUDs"). Guidant has serious concerns about the continued safety and effectiveness of heart stabilizer devices after reprocessing, especially with regard to the risk of cross-contamination and the deterioration of the mechanical properties of the devices.

B. FDA Classification of Reprocessed Single Use Heart Stabilizers

On April 30, 2003, as required by MDUFMA, FDA published a list of critical devices, *i.e.*, RSUDs that are intended to contact normally sterile tissue or body spaces during use, whose 510(k) exemption will be terminated. *See Medical Devices; Reprocessed Single-Use Devices; Termination of Exemptions From Premarket Notification; Requirement for Submission of Validation Data*, 68 Fed. Reg. 23,139 (Apr. 30, 2003) [hereinafter *Federal Register Notice*]. In deciding which critical RSUDs would lose their 510(k) exemption, FDA applied the Review Prioritization Scheme ("RPS") set forth in FDA's draft guidance entitled "*Reprocessing and Reuse of Single-Use Devices: Prioritization Scheme*" dated February 8, 2000 (the "Guidance Document"). In accordance with the RPS, FDA assigned an overall risk to each critical RSUD based on: (1) the risk of infection; and (2) the risk of inadequate performance after reprocessing. Id. at 23,140. 1/ Based

1/ FDA also used one other criterion not pertinent to heart stabilizer devices, *i.e.*, whether the device comes into contact with tissue at high risk of being infected with the causative agents of Creuzfeldt-Jakob Disease (CJD). *Federal Register Notice* at 23,140.

on these factors, FDA established three risk categories for RSUDs: high; moderate; and low. Id. Only those critical RSUDs that were classified as "high" risk devices, because they posed the greatest risk of infection and/or inadequate performance after reprocessing, were included on the List of critical RSUDs whose exemption will be terminated. Id.

Reprocessed single use heart stabilizer devices have been classified as "critical" devices because they are intended to contact normally sterile tissue or body spaces during use. FDA, however, did not include heart stabilizer devices on the List of critical RSUDs from which 510(k) exemption will be withdrawn. Instead, FDA classified these products as "moderate" risk devices. *Federal Register Notice* at 23,143. FDA acknowledged, however, that the Agency may need to reevaluate and update this List of critical RSUDs and stated that it will consider comments from the public on additional devices that should be included on the List at any time. Id. at 23,141.

II. FDA SHOULD REQUIRE 510(K) SUBMISSIONS FOR REPROCESSED SINGLE USE HEART STABILIZER DEVICES

FDA should require 510(k) submissions for reprocessed single use heart stabilizer devices because of the potential high risk of infection and potential high risk of inadequate performance associated with the reprocessing of these devices. Based on the Review Prioritization Scheme set forth in FDA's Guidance Document, reprocessed single use heart stabilizer devices are more appropriately classified as "high" risk devices, rather than "moderate" risk devices, because they pose the greatest potential risk of infection and/or inadequate performance after reprocessing. Accordingly, reprocessed single use heart stabilizer devices should be included on the List of critical RSUDs from which 510(k) exemption will be withdrawn.

A. Risk of Infection

Reprocessed heart stabilizer devices present a potential high risk of infection because they include features that could impede thorough cleaning and

adequate sterilization. In particular, heart stabilizer devices incorporate components that have narrow lumens, interlocking parts, and small crevasses that are likely to trap blood and body tissue during normal use and that are not easily accessed and removed during cleaning. For example, heart stabilizer devices that use suction to attach tissue to the device incorporate a suction cup that is connected by narrow tubing (*e.g.*, ¼ inch diameter) to a vacuum source. During normal use, blood and body tissue is drawn into this narrow tubing and collected in a fluid collection canister. Likewise, the flexible arm of heart stabilizer devices consists of interlocking rings that are in direct contact with blood and body tissue. During use, the flexible arm is locked into position by turning a knob that tightens the cable inside the arm. Although the interlocking rings may be loosened and the arm readjusted, the interlocking rings of the flexible arm cannot be disassembled completely without damaging the device. Finally, many heart stabilizer devices incorporate retractors on which a flexible arm may be mounted. To allow for anchoring of sutures used during the procedure, many retractors incorporate small (*e.g.*, approximately 1 x 3 mm (width x depth)) grooves and indentations that are exposed to blood and body tissue during use. The narrow tubing, interlocking rings of the flexible arm, and grooves and indentations of the retractor may harbor blood and body tissue after use and are not easily accessed and removed during cleaning. Because these components of heart stabilizer devices are difficult to clean, terminal processing to sterilize such devices may not be successful and such reprocessed devices present a potential high risk of infection. These devices as properly manufactured single use devices are safe and effective but the safety and efficacy of reprocessed devices is problematic.

In addition, no recognized consensus performance standards, performance tests recommended by manufacturers, or Center for Devices and Radiological Health ("CDRH") guidance documents exist that may be used to determine if a reprocessed heart stabilizer has been adequately cleaned and sterilized. Therefore, according to the Review Prioritization Scheme set forth in the Guidance Document, reprocessed heart stabilizer devices present a high risk of infection and should be included on the List. A flowchart applying the Review Prioritization Scheme to determine the risk of infection presented by reprocessed heart stabilizer devices is provided in **Attachment 1**.

B. Risk of Inadequate Performance After Reprocessing

Reprocessed heart stabilizer devices also present a potential high risk of inadequate performance after reprocessing because the failure of such devices could cause death, serious injury, or permanent impairment. In addition, such devices contain materials, coatings, or components that may be damaged or altered by reprocessing in such a way that performance of the device may be adversely affected. In particular, initial use and/or reprocessing of heart stabilizer devices may weaken the adhesive bond strength of the feet (plastic and metal bonding) causing the feet to break off during reuse. In addition, single use and/or reprocessing of these devices could potentially reduce the strength of the flexible arm. For example, the torque limiter employed in the flexible arm of many heart stabilizer devices may be adversely affected by initial use and/or reprocessing resulting in inadequate stability during reuse. Moreover, there exist no recognized consensus performance standards, performance tests recommended by manufacturers, or CDRH guidance documents that may be used to determine if the reprocessed device has been altered due to reprocessing. Finally, visual inspection alone cannot determine if reprocessing has altered the performance of heart stabilizer devices. For example, a weakening of the adhesive bond strength of the malleable feet of heart stabilizer devices may not be visible prior to reuse. Likewise, a reduction in the strength and stability of the flexible arm may not be obvious until actual use of the reprocessed device on a patient, or until adequate torque tensile testing is conducted after reprocessing. Thus, according to the Review Prioritization Scheme set forth in the Guidance Document, reprocessed heart stabilizer devices present a high risk of inadequate performance and should be included on the List. A flowchart applying the Review Prioritization Scheme to determine the risk of inadequate performance presented by reprocessed heart stabilizer devices is provided in **Attachment 2**.

III. CONCLUSION

In sum, reprocessed heart stabilizer devices are "critical" devices that present a high risk of infection and a high risk of inadequate performance after reprocessing. Accordingly, these devices should be included on the List of reprocessed single use devices previously exempt from premarket notification

requirement that will now require 510(k)s with validation data. We will contact you shortly to discuss FDA's response to this request. In the interim, please direct any questions or requests for additional information concerning this letter to me at (202) 637-5794.

Sincerely,

Jonathan S. Kahan

cc: Greg Garfield, Guidant Corporation
Jeffrey K. Shapiro, Esq.

ATTACHMENT 1

EVALUATION OF INFECTION RISK /FLOWCHART 1

High Risk SUD: Heart Stabilizer Device (870.4500 MWS)

Question 1: Are heart stabilizers non-critical devices?

The answer to Question 1 is "No" because heart stabilizers make contact with a normally sterile area.

Go to Question 2.

Question 2: Does FDA have postmarket data that suggest using a reprocessed heart stabilizer may present an increased risk of infection?

At this time, the Company does not know of any postmarket data that suggest using a reprocessed heart stabilizer may present an increased risk of infection when compared to the use of a heart stabilizer that has not been reprocessed.

The answer to Question 2 is "No."

Go to Question 3.

Question 3: Does a heart stabilizer have features that may impede cleaning and disinfection or sterilization?

Heart stabilizers have features that could impede thorough cleaning and adequate sterilization. In particular, heart stabilizer devices incorporate components that have narrow lumens, interlocking parts, and small crevasses that are likely to trap blood and body tissue during normal use. For example, heart stabilizer devices that use suction to attach tissue to the device incorporate a suction cup that is connected by narrow tubing (*e.g.*, ¼ inch diameter) to a vacuum source. During normal use, blood and body tissue is drawn into this narrow tubing and collected in a fluid collection canister. Likewise, the flexible arms of heart stabilizer devices consist of interlocking rings that may harbor blood and body tissue after use. During use, the flexible arm is locked into position

by turning a knob that tightens the cable inside the arm. Although the interlocking rings may be loosened and the arm readjusted, the interlocking rings of the flexible arm cannot be disassembled completely without damaging the device. Finally, many heart stabilizer devices incorporate retractors on which a flexible arm may be mounted. To allow for anchoring of sutures used during the procedure, many retractors incorporate small (*e.g.*, approximately 1 x 3 mm (width x depth)) grooves and indentations that are exposed to blood and body tissue during use. The narrow tubing, interlocking parts, and small grooves and indentations of these components cannot be readily accessed and removed during cleaning. Because these components are difficult to clean, terminal processing to sterilize such devices may not be successful.

The answer to Question 3 is "Yes."

Go to Question 4.

Question 4: Does a reusable device exist that has an equivalent design and the same intended use?

Heart stabilizer devices include vacuum positioners, vacuum stabilizers, and mechanical stabilizers. At this time the Company does not know of any entirely reusable vacuum positioners or vacuum stabilizers. The Company is aware of reusable mechanical stabilizers, and other stabilizers that include reusable components. However, unlike single use stabilizers, many of these reusable stabilizers and reusable components consist of different materials and design features than single use devices. Accordingly, at this time the Company does not know of any reusable heart stabilizer devices with an equivalent design and the same intended use as heart stabilizer devices manufactured by the Company.

The answer to Question 4 is "No."

Go to Question 5.

Question 5: Are there recognized standards that may be used to determine if the SUD has been adequately cleaned and sterilized?

At this time there are no recognized consensus performance standards, tests recommended by the manufacturer, or CDRH guidance documents that may be used to determine if a heart stabilizer has been adequately cleaned and sterilized for reuse.

The answer to Question 5 is "No."

Go to Question 6.

Question 6: Is this a semi-critical device?

The answer to Question 6 is "No." Heart stabilizers are critical devices.

Therefore, heart stabilizers pose a high risk of infection if reprocessed and reused.

ATTACHMENT 2

EVALUATION OF RISK OF INADEQUATE PERFORMANCE/FLOWCHART 2

High Risk SUD: Heart Stabilizer Device (870.4500 MWS)

Question 1: Does postmarket information suggest there is an increased risk of injury when compared to the use of a single use device that has not been reprocessed?

The Company is not aware of any postmarket information that establishes that there is an increased risk of injury.

The answer to Question 1 is "No."

Go to Question 2.

Question 2: Could failure of the device cause death, serious injury, or permanent impairment?

Failure of a heart stabilizer could cause death, serious injury or permanent impairment.

The answer to Question 2 is "Yes."

Go to Question 3.

Question 3: Do heart stabilizers contain any materials, coatings, or components that may be damaged or altered by a single use or by reprocessing and/or resterilization/disinfection in such a way that the performance of the device may be adversely affected?

Heart stabilizers do contain materials, coatings, or components that may be damaged or altered by reprocessing in such a way that performance of the device may be adversely affected. In particular, initial use and/or reprocessing of heart stabilizer devices may weaken the adhesive bond strength of the feet (plastic and metal bonding). In addition, single use and/or reprocessing of these devices could potentially reduce the strength of the flexible arm. For example, the torque limiter employed in the flexible arm of

many heart stabilizer devices may be adversely affected by initial use and/or reprocessing.

The answer to Question 3 is "Yes."

Go to Question 4.

Question 4: Are there recognized consensus performance standards, performance tests recommended by the OEM, or a CDRH guidance document that may be used to determine if the performance of the SUD has been altered due to reprocessing and use?

There are no such standards, tests, or CDRH guidance documents.

The answer to Question 4 is "No."

Go to Question 5.

Question 5: Can visual inspection determine if performance has been affected?

Critical failure of heart stabilizers is not always visual or self-evident. For example, a weakening of the adhesive bond strength of the malleable feet of heart stabilizer devices may not be visible prior to reuse or until adequate torque tensile testing is conducted after reprocessing. Likewise, a reduction in the strength and stability of the flexible arm may not be obvious until actual use of the reprocessed device on a patient.

The answer to Question 5 is "No."

Thus, heart stabilizers pose a high risk of inadequate performance if reprocessed and reused.