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

**Re: Request for Inclusion of All Reprocessed Endoscopic
Vein Harvesting Devices on Validation List
(Docket No. 03N-0161)**

To Whom It May Concern:

On behalf of Guidant Corporation ("Guidant" or the "Company"), we are writing to request that the Food and Drug Administration ("FDA" or the "Agency") revise the List of Reprocessed Single-Use Devices Subject to Premarket Notification Requirements that Will Now Require the Submission of Validation Data (the "Validation List") published in the Federal Register on April 30, 2003, to provide for consistent treatment of endoscopic vessel harvesting devices. See *Medical Devices; Reprocessed Single-Use Devices; Termination of Exemptions From Premarket Notification; Requirement for Submission of Validation Data*, 68 Fed. Reg. 23,139 at 23,142 (Apr. 30, 2003) [hereinafter *Federal Register Notice*]. Specifically, we request that FDA include endoscopic vessel harvesting devices classified under 21 C.F.R. § 878.4400 ("Electrosurgical cutting and coagulation device and accessories") and assigned product code "GEI" on the Validation List, in addition to those endoscopic vessel harvesting devices classified under 21 C.F.R. § 876.1500 ("Endoscope and accessories") and assigned product code "GCJ" that appeared on the list when it originally was published.

Endoscopic vessel harvesting devices classified by FDA as electrosurgical cutting and coagulation devices should be included on the Validation List because they present the same potential risk of infection and potential risk of inadequate performance after reprocessing as those vein harvesting devices classified simply as endoscopes that were listed; accordingly, reproprocessors of these

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devices should be required to demonstrate with validation data that their reprocessing methods effectively mitigate these risks, ensuring that the products remain substantially equivalent to their predicate devices. In the alternative, those endoscopic vessel harvesting devices that have been designated by FDA as electrosurgical cutting and coagulation devices (under product code "GEI") could be recoded by the Agency as endoscopes and assigned product code "GCJ," which would achieve the same effect, again creating a requirement that reprocessors of these devices provide validation data to FDA to demonstrate their substantial equivalence after reprocessing.

I. FACTUAL BACKGROUND

A. Device Description

As noted above, possibly through oversight, FDA has classified some endoscopic vessel harvesting devices as "electrosurgical cutting and coagulation devices" under 21 C.F.R. § 878.4400 while others have been classified as "endoscope devices," under 21 C.F.R. § 876.1500. These devices have been assigned the product codes "GEI" and "GCJ" respectively. Specifically, Guidant's VasoView 5 Harvesting Cannula (K020143) and VasoView 6 Harvesting Cannula (K022718) were classified by FDA as electrosurgical cutting devices under 21 C.F.R. § 878.4400 and placed by the Agency in product code "GEI" ^{1/}. These two devices have identical intended uses ("cutting and coagulation of tissue and providing access in minimally invasive vessel harvesting procedures for patients undergoing coronary artery bypass grafting," according to the 510(k) Summaries for each device) and virtually identical

^{1/} The VasoView 5 appears in FDA's 510(k) database under product code "HET," the code for Gynecologic Laparoscopes. However, the clearance letter assigns it product code "GEI" and describes it as an electrosurgical cutting and coagulation device. We believe the listing of VasoView 5 in the 510(k) database under product code "HET" was the result of a typographical error by the Agency.

technological characteristics 2/. The cleared Indications for Use for the devices also are identical:

The VasoView 5 [or 6] has applications in minimally invasive surgery and is primarily indicated for patients undergoing endoscopic surgery for vessel harvesting. It is indicated for cutting tissue and controlling bleeding through coagulation in general and cardiothoracic surgery including minimally invasive direct coronary artery bypass (MIDCAB), lower extremity and thoracoscopic procedures. Lower extremity procedures include tissue dissection, vessel harvesting along the saphenous vein for use in coronary artery bypass grafting and peripheral artery bypass. Thoracoscopic procedures include exposure and dissection of structures external to the parietal pleura, including nerves, blood vessels, and other tissues of the chest wall.

By contrast, Guidant's VasoView Dissection/Vessel Harvesting System ("VasoView Dissection System") (K981700) and VasoView Endoscopic Vessel Harvesting System (K030512) were cleared by FDA under product code "GCJ," which appears on the Validation List. 3/ Similar to the VasoView 5 and VasoView 6 Harvesting Cannulas, the VasoView Dissection System is indicated for use "in minimally invasive surgery allowing access for vessel harvesting, and is primarily indicated for patients undergoing endoscopic vessel harvesting for arterial bypass." The VasoView Dissection System's indication statement continues as follows:

2/ The VasoView 6 is identical to the VasoView 5 with the exception of the modification of the blades and electrode configuration, addition of bipolar rotation, and insufflation capability through the cannula.

3/ The VasoView Dissection System appears in FDA's Device Listing database under product code "KOG"; however, the clearance letter designates it as a "GCJ" device. We believe the code designation in the Device Listing also is an error.

[The VasoView Dissection System] is indicated for patients undergoing endoscopic surgery requiring tissue separation of the extraperitoneal or subcutaneous extremity and thoracic space. Extremity procedures include tissue dissection/vessel harvesting along the saphenous vein and the femoral vessels. Thoracoscopic procedures include exposure and dissection of structures external to the parietal pleura, including nerves, blood vessels, and other tissues of the chest wall.

The VasoView Endoscopic Vessel Harvesting System contains a primary indication statement that is virtually identical to that of the VasoView Dissection System (the device is indicated for use “in minimally invasive surgery allowing access for vessel harvesting, and is primarily indicated for patients undergoing endoscopic surgery for arterial bypass.”) It is further indicated for use in patients:

... requiring blunt dissection of tissue including dissection of blood vessels, separation of the extraperitoneal or subcutaneous extremity and thoracic space. Extremity procedures include tissue dissection along the saphenous vein or radial artery for use in coronary artery bypass grafting. Thoracoscopic procedures include exposure and dissection of structures external to the parietal pleura, including nerves, blood vessels, and other tissues of the chest wall.

Thus, all four VasoView vessel harvesting systems are used in endoscopic procedures on patients who are undergoing arterial bypass surgery. Furthermore, the specific Indications for Use of each device are extremely similar.

Regardless of their product code assignment, all of Guidant's endoscopic vessel harvesting devices share the following characteristics: they use multi-lumen cannulas to manipulate and cauterize vessels as their principal mode of operation. Generally, these devices are used in variable combinations that consist of a port, multi-lumen cannulas, endoscopes, bipolar scissors, bisectors, tissue welders, and other accessories to perform techniques for vessel manipulation, branch coagulation, and division. These

components are exposed to blood and body tissue during use and incorporate interchangeable assemblies, retracting parts, long narrow lumens, cautery surfaces, 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 particular washing in strong detergents or dismantling components, in such a way that performance of the device may be adversely affected by the reprocessing.

Although the endoscopic vessel harvesting devices manufactured by Guidant are labeled and sold as single use devices, the Company has learned that several reprocessing companies are sterilizing these products after use and reselling them as reprocessed single use devices ("RSUDs").

B. FDA's Treatment of Reprocessed Single Use Endoscopic Vessel Harvesting Device under the Review Prioritization Scheme

On April 30, 2003, as required by the Medical Device User Fee and Modernization Act of 2002 ("MDUFMA"), FDA published a list of RSUDs already subject to premarket notification requirements for which validation data would be required to ensure their substantial equivalence to predicate devices. These devices, which may have been designated by FDA as critical, semi-critical or non-critical, were chosen on the basis of the overall risk they presented, as defined in 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 level to each RSUD based on: (1) the risk of infection; and (2) the risk of inadequate performance after reprocessing. *Id.* at 23,140. Based on these factors, FDA established three risk categories for RSUDs: high, moderate, and low. *Id.* Only those RSUDs that were classified as "high" risk devices, because they posed the greatest risk of infection and/or inadequate performance after reprocessing (or were intended to come into contact with tissues at high risk of being infected with the causative agents of Creutzfeldt-Jakob Disease ("CJD")), were included on the Validation List. *Id.*

FDA classified "GCJ" endoscopes as "high" risk devices under the RPS. *Id.* at 23,146. By contrast, electrosurgical cutting and coagulation devices and accessories (assigned product code "GEI") – like the VasoView 5 and VasoView 6

Harvesting Cannulas – were deemed to be “moderate” risk devices. *Id.* at 23,147. FDA did not provide any additional information in the Federal Register Notice to justify or support the distinction it made between these two device types.

FDA acknowledged in the Federal Register Notice that the Agency may need to reevaluate and update the Validation List 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 THE SUBMISSION OF 510(K)S WITH VALIDATION DATA FOR ALL REPROCESSED SINGLE USE ENDOSCOPIC VESSEL HARVESTING DEVICES

FDA should require 510(k) submissions for all reprocessed single use endoscopic vessel harvesting devices because of the potential high risk of infection and potential high risk of inadequate performance associated with the reprocessing of these devices. Under the RPS, reprocessed single use endoscopic vessel harvesting devices are appropriately classified as “high” risk devices, because they pose the greatest potential risk of infection and/or inadequate performance after reprocessing. However, as noted above, while some endoscopic vessel harvesting devices (the “GCJ” devices) were classified as high risk devices, others (the “GEI” devices) were classified as moderate risk devices, despite the fact that they present the same high potential for risk of infection and/or inadequate performance after reprocessing. Accordingly, to provide consistent regulatory treatment of products that present comparable risks on reuse and to resolve this anomalous situation, all reprocessed single use endoscopic vessel harvesting devices (including both those designated by FDA as endoscopes in product code “GCJ” and those designated as electrosurgical cutting and coagulation devices in product code “GEI”) should be included on the Validation List.

A. Risk of Infection

Reprocessed endoscopic vessel harvesting devices present a potential high risk of infection because they include features that could impede thorough cleaning and adequate sterilization. In particular, endoscopic vessel harvesting devices incorporate components that have long narrow lumens, retracting parts,

cautery surfaces, 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, endoscopic vessel harvesting devices have components that can be extended and retracted through narrow lumens.

During normal use, blood and body tissue is drawn into these narrow lumens. Likewise, to wash the scope during use, saline is flushed into the site through one port, and is removed through a vacuum port. Thus, during normal use, blood and body tissue also is drawn into this vacuum port. Additionally, during use of these devices, the cautery surfaces develop a layer of electrified blood and body tissue which is very difficult to remove. Finally, the device consists of interchangeable subassemblies which have many small crevasses and narrow winding cavities. These crevasses and cavities may harbor blood and body tissue after use that are not easily accessed or removed during cleaning. Because these components of endoscopic vessel harvesting 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.

In addition, no recognized consensus of 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 endoscopic vessel harvesting device has been adequately cleaned and sterilized. Therefore, according to the RPS, reprocessed endoscopic vessel harvesting devices present a high risk of infection and should be included on the Validation List. A flowchart applying the RPS to determine the risk of infection presented by reprocessed endoscopic vessel harvesting devices is provided in **Attachment 1**.

B. Risk of Inadequate Performance after Reprocessing

Reprocessed endoscopic vessel harvesting devices also present a potential high risk of inadequate performance after reprocessing because the failure of such devices could cause 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. Furthermore, multiple use and/or reprocessing of these devices could potentially reduce the functionality of the cutting devices. For example, the

force required to activate the bipolar scissors increases greatly after a set number of cycles, and thus the scissors may not be suitable for 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 endoscopic vessel harvesting devices. For example, a weakening of the adhesive bond strengths throughout the devices may not be visible prior to reuse. Likewise, a reduction in the component integrity and electrical insulation may not be obvious until actual use of the reprocessed device on a patient.

Thus, according to the RPS, reprocessed endoscopic vessel harvesting devices present a high risk of inadequate performance and should be included on the Validation List. A flowchart applying the RPS to determine the risk of inadequate performance presented by reprocessed endoscopic vessel harvesting devices is provided in **Attachment 2**.

III. CONCLUSION

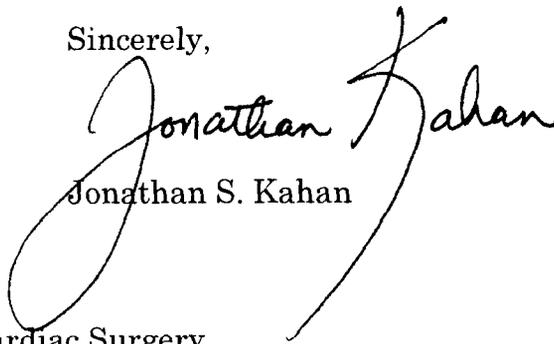
In summary, reprocessed endoscopic vessel harvesting devices present a high risk of infection and a high risk of inadequate performance after reprocessing, regardless of whether FDA considers them to be endoscopes or electrosurgical cutting and coagulation devices for product classification and coding purposes. Accordingly, we believe that endoscopic vessel harvesting devices assigned product code "GEI," like those assigned product code "GCJ," should be included on the Validation List. In the alternative, we would request that FDA recode the VasoView 5 and VasoView 6 Harvesting Cannulas as endoscopes (under product code "GCJ"), so that reprocessors of these devices would be required to provide validation data demonstrating that they remain substantially equivalent upon reuse.

John Allison, Vice President of Regulatory & Clinical Affairs, Quality Assurance and Compliance at Guidant Cardiac Surgery, and I would be happy to discuss these issues directly with FDA if the Agency believes that would be helpful.

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Please contact me at the number above or Karen Bates at (202) 637-5897 if you would like to schedule a conference call or meeting.

Sincerely,


Jonathan S. Kahan

cc: John B. Allison, Guidant Cardiac Surgery
Karen C. Bates, Hogan & Hartson, L.L.P.