K041981

AUG 2 0 2004

Appendix A – 510(k) Summary

Submitter	Guidant Corporation, Cardiac Surgery
Submitter's Address	3200 Lakeside Drive Santa Clara, CA 95054
Telephone	(408) 845-2014
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Contact Person	M. Laurie Wong
Date Prepared	July 22, 2004
Device Trade Name	Guidant VasoView® 6 Harvesting Cannula
Device Common Name	Electrosurgical cutting and coagulation device and accessories
Device Classification Name	Electrosurgical cutting and coagulation device and accessories
Device Classification	Class II
Summary of substantial equivalence	The design, materials, method of delivery, and intended use features of the Guidant VasoView 6 Harvesting Cannula are substantially equivalent with regard to these features in the predicate devices: the VV4 (K030512, May 14, 2003), VV5 (K020143, February 20, 2002), and VV6 (K022718, August 28, 2002).

Device description	The Guidant VasoView® 6 Harvesting Cannula is designed for use in conjunction with the 7 mm Endoscope. The Harvesting Cannula has four lumens which house the Endoscope, C-Ring wire, endoscope washer tube and Bipolar Bisector for ligation and division of vessel branches. The C-Ring/endoscope washer is independently controlled by a C-Ring Slider on the handle of the device for retraction of the vessel as well as washing of the distal tip of the Endoscope. The Bipolar Bisector can be extended/retracted/rotated with the Bisector Carriage, and mechanical cutting is achieved with the toggle located on the Bisector Carriage. Bipolar coagulation is achieved using electrosurgical energy. Positioning of the device, coagulation, and mechanical cutting are performed under endoscopic visualization. This device is intended for use with the bipolar outputs of compatible generators.
Indications for Use	The VasoView® 6 System 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 indicated for cutting tissue and controlling bleeding through coagulation, and for patients requiring blunt dissection of tissue including dissection of blood vessels, dissection of blood vessels of the extremities, dissection of ducts and other structures in the extraperitoneal or subcutaneous extremity and thoracic space. Extremity procedures include tissue dissection/vessel harvesting along the saphenous vein for use in coronary artery bypass grafting and peripheral artery bypass 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.
Technological characteristics	Guidant VasoView 6 Harvesting Cannula incorporates the same fundamental scientific technology as the predicate devices.
Performance data	The results of the verification testing demonstrate that the Guidant VasoView 6 Harvesting Cannula meet the established acceptance criteria and performs in a manner equivalent to the predicate devices. No new safety or effectiveness issues were raised during the testing program.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 0 2004

Ms. M. Laurie Wong
Sr. Regulatory Affairs Specialist
Guidant Corporation
Cardiac Surgery
3200 Lakeside Drive
Santa Clara, California 95054

Re: K041981
Trade/Device Name: Guidant VasoView® 6 Harvesting Cannula , Model VH-2000: Guidant VasoView® 6
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: July 22, 2004
Received: July 23, 2004

Dear Ms. Wong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041981

Device Name: Guidant VasoView® 6 Harvesting Cannula, Model VH-2000: Guidant VasoView® 6

Indications For Use:

The VasoView® 6 System 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 indicated for cutting tissue and controlling bleeding through coagulation, and for patients requiring blunt dissection of tissue including dissection of blood vessels, dissection of blood vessels of the extremities, dissection of ducts and other structures in the extraperitoneal or subcutaneous extremity and thoracic space. Extremity procedures include tissue dissection/vessel harvesting along the saphenous vein for use in coronary artery bypass grafting and peripheral artery bypass 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.

for Mark N. Milhem

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041981

Prescription Use ✓ AND/OR Over-The-Counter Use ___No___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)