AUG 2 8 2002

K022718

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

A. Name, Address, Phone and Fax number of the Applicant

Guidant Corporation
Cardiac Surgery
3200 Lakeside Drive
Santa Clara, CA 95054

Telephone: (408) 845-1842
Fax: (408) 845-1855

B. Contact Person

Anne Schlagenhaft
Regulatory Affairs Associate

C. Date Prepared

July 22, 2002

D. Device Name

Trade Name: VasoView® 6 Harvesting Cannula
Classification Name: Electrosurgical cutting and coagulation device and accessories

E. Device Description

The VasoView 6 Harvesting Cannula is a disposable device designed to perform endoscopic cutting and coagulation, including vessel isolation and division of vessel branches. The device has a tubular cannula for introduction of instrumentation into the surgical site with a proximal handle to hold and control the device during procedures. A lumen of the cannula allows insertion of an endoscope for illumination and visualization of the procedure. Extension, retraction and actuation of the transector cutting and coagulation tool is achieved with controls located on the handle.

F. Intended Use

The VasoView 6 Harvesting Cannula is intended for cutting and coagulation of tissue and providing access in minimally invasive vessel harvesting procedures for patients undergoing coronary artery bypass grafting.

G. Substantial Equivalence

The VasoView 6 Harvesting Cannula is substantially equivalent to the VasoView 5 Harvesting Cannula, cleared by the Food and Drug Administration under K020143 on February 20, 2002. The design of the VasoView 6 Harvesting Cannula is identical to the current device with the exception of the modification of the blades and electrode configuration, addition of bipolar tool rotation, and insufflation capability through the cannula. The VasoView 6 Harvesting Cannula is substantially equivalent to the predicate devices in intended use, technological characteristics, materials, manufacturing processes, and components.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 8 2002

Guidant Corporation
c/o Ms. Michelle Weidman
Kema Medical
4377 County Line Road
Chalfont, PA 18914

Re: K022718
Trade/Device Name: Vaso View® 6 Harvesting Cannula
Regulation Number: 878.4400
Regulation Name: Electrosurgical cutting and coagulating device and accessories
Regulatory Class: II
Product Code: GEI
Dated: July 22, 2002
Received: August 15, 2002

Dear Ms. Weidman:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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

510(k) Number (if known): K 022718

Device Name: VasoView® 6 Harvesting Cannula

Indications For Use:

The VasoView® 6 Harvesting Cannula 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.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ Over-The-Counter Use

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

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

510(k) Number K022718