MAY 1 4 2003

510(k) SUMMARY

K030512

This summary of 510(k) safety and effectiveness information is submitted in accordance3 with the requirements of SMDA 1990 and 21 CFR 8078.92.

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

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

Telephone: (408) 845-1910
Fax: (408) 845-1800

B. Contact Person

Nancy Lincé
Regulatory Affairs Consultant

C. Date Prepared

February 14, 2003 (revised May 1, 2003)

D. Device Name

Trade Name: Guidant VasoView System
Classification Name: Surgical Trocar, Cannula, Electrosurgical Devices and Endoscopes

E. Device Description

The VasoView System is made up of 6 components including:

1) Blunt Tip Trocar (BTT) with Syringe,
2) 5 mm Extended Length Endoscope,
3) Uniport Plus Dissection Cannula,
4) VasoView Dissection Cannula,
5) Uniport BiSector and
6) Uniport Bipolar Scissors.

These are the exact same devices used for saphenous vein harvesting and have been previously cleared by FDA. Each device is described below.

BTT:

The BTT is a single use device provided sterile. The BTT is used to provide a port of access for insertion of endoscopic instruments into an incision site. The device consists of a valve body assembly with a balloon on the sleeve. The valve body assembly contains an internal flapper valve and seal to prevent gas leakage when instruments are

inserted or withdrawn. It also includes built-in converters to allow insertion of instruments of different diameters than the main seal and an external one-way valve for gas insufflation. To minimize leakage and secure the port, the distal end of the sleeve has a balloon. A 30cc syringe is provided for inflation/deflation of the balloon.

5mm Extended Length Endoscope:
The 5mm Extended Length Endoscope is a multi-use product supplied non-sterile and must be cleaned and sterilized prior to use. The device is used to visualize endoscopic cavities. It consists of a stainless steel shaft containing optics. The proximal end has an eyepiece, for camera attachment, and a light cable post for light cable connection.

Uniport Plus Dissection Cannula
The Uniport Plus Dissection Cannula is a single use device provided sterile. The Uniport Plus Dissection Cannula is designed to be used in conjunction with the 5mm Extended Length Endoscope. The cannula has a removable conical tip and four lumens to house the endoscopes, vessel cradle/distal lens washer and bipolar instrument for ligation and division of vessel branches. The vessel cradle/distal lens washer is independently controlled by a slider button on the handle of the device for retraction and blunt dissection of tissue as well as washing of the distal tip of the scope. The bipolar instrument is inserted independently into the cannula and can be controlled at the proximal end for blunt dissection.

Dissection System:
The Dissection System is a single-use device provided sterile. It is designed to be used in conjunction with a 5mm Extended Length Endoscope. The cannula has a tapered tip for tunneling, which separates tissue planes, forming a cavity. The cannula tip may also be used for dissection and isolation of structures in the cavity. This tip is clear for endoscopic visualization during tunneling. An elliptical bulb aid tissue separation. A handle is provided to assist with advancement of the cannula.

Uniport BiSector:
The Uniport BiSector is a single use device provided sterile. The Uniport BiSector is a 5mm flexible endoscopic ligating forcep and is intended to be used with the Uniport Dissection Cannula. Bipolar coagulation is achieved using electro surgical energy under endoscopic visualization. Transection is achieved through mechanical actuation of the slide button. This device is intended to be used with the bipolar outputs of compatible generators.

Bipolar Scissors:
The Bipolar Scissors are a single use device provided sterile. The Bipolar Scissors are 5mm cutting and bipolar coagulation scissors and are intended to be used with the Dissection Cannulas. Mechanical cutting and bipolar coagulation is achieved using electrosurgical energy under endoscopic visualization. This device is intended to be used with the bipolar outputs of compatible generators.

F. Intended Use

The Guidant VasoView® Endoscopic Vessel harvesting 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 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.

G. Substantial Equivalence

The Guidant VasoView Endoscopic Vessel Harvesting System submitted under this 510K application is substantially equivalent to the predicated devices in intended use, indications, technological characteristics, labeling and packaging materials, and manufacturing processes. The technological characteristics, packaging materials and manufacturing processes are unchanged from 510K numbers K904993, K945975, K960637, K974608, K981700 and K992353, their amendments and supplements. All devices are cleared through FDA or exempt. The present submission is limited to an indication expansion. The clinical data presented in the submission demonstrates that the Guidant VasoView Endoscopic Vessel Harvesting System does no raise new questions of safety and effectiveness when used to perform the expanded indication of radial artery harvesting.

H. Device Testing Results and Conclusion

The pre-clinical testing information for the VasoView System devices is unchanged from 510K numbers K904993, K945975, K960637, K974608, K981700 and K992353, their amendments and supplements. All devices are cleared through FDA or exempt. The present submission is limited to an indication expansion, which does not affect the pre-clinical testing.

The results of over 84 cases demonstrate that the Guidant VasoView Vessel Harvesting System is a safe and effective approach to endoscopic radial artery harvesting. Furthermore, the safety and efficacy of performing radial artery harvesting using the endoscopic approach has been well demonstrated and presented.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 14 2003

Ms. Nancy Lincé
Regulatory Affairs Consultant
Guidant Corporation
Cardiac Surgery
3200 Lakeside Drive
Santa Clara, California 95054

Re: K030512
Trade/Device Name: Guidant VasoView Endoscopic Harvesting System
Regulation Number: 21 CFR 876.1500
Regulation Names: Endoscope and accessories
Regulatory Class: II
Product Codes: GCJ
Dated: February 17, 2003
Received: February 19, 2003

Dear Ms. Lincé:

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. 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) you may obtain. 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,

Miriam C. Provost

for 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

Guidant Corporation **510(k) Premarket Notification Supplement**
Cardiac Surgery **Guidant VasoView Endoscopic Vessel Harvesting System**

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K030512

Device Name: Guidant VasoView Endoscopic Harvesting System

Indications For Use:

The Guidant VasoView® Endoscopic Vessel harvesting 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 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. Thorascopic 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 ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)
(Optional Format 1-2-96)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K030512