510(K) SUMMARY

K014250

JAN 1 0 2002

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
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B. Contact Person

Anne Schlagenhaft
Regulatory Affairs Associate

C. Date Prepared

December 4, 2001

D. Device Name

Trade Name: 7 mm Extended Length Endoscope

Classification Name: Endoscope and accessories

E. Device Description

The 7 mm Extended Length Endoscope consists of an elongated shaft that houses glass fibers for light delivery and an achromatic optical lens system (enclosed within the shaft and proximal hub) for image return. The distal shaft has a window for viewing and threads for attachment of the Dissection Tip. The proximal hub has a light guide post for attachment of light guides and an eyepiece with a clear viewing window for attachment of medical camera couplers. The Endoscope provides illumination and visualization of the working space during tissue dissection, vessel ligation, and vessel transection. With the Dissection Tip attached, the Endoscope is used to perform blunt dissection to separate tissue. The distal tip of the

Endoscope has threads on the scope body for attachment of the Dissection Tip. The Dissection Tip may be removed once dissection is completed so that the Endoscope can continue to be used for visualization of a procedure.

F. Intended Use

The 7 mm Extended Length Endoscope is intended for visualization of a surgical working cavity in minimally invasive surgery allowing access for vessel harvesting, and is primarily indicated for patients undergoing endoscopic vessel harvesting for arterial bypass. It 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.

G. Substantial Equivalence

The 7 mm Extended Length Endoscope with Dissection Tip is substantially equivalent to the 5mm Endoscope, cleared by the Food and Drug Administration under K960637 on June 14, 1996, and the VasoView™ Dissection Cannula, K981700, cleared on February 18, 1998. The design of the 7 mm Extended Length Endoscope with Dissection Tip is identical to the current Endoscope with a thicker scope body wall and incorporation of the dissection cone of the VasoView Dissection Cannula. The subject device is composed of materials that are identical to the currently marketed devices. The 7 mm Extended Length Endoscope is substantially equivalent in intended use, materials, manufacturing processes, technological characteristics, and components to the current devices.

H. Device Testing Results and Conclusion

All necessary testing was performed on the 7 mm Extended Length Endoscope with Dissection Tip to ensure that the product is substantially equivalent to the predicate devices and that the modifications do not affect safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 0 2002

Guidant Corporation
c/o Ms. Michelle Weidman
KEMA Medical
4377 County Line Road, Suite 202
Chalfont, Pennsylvania 18914

Re: K014250
Trade/Device Name: 7 mm Extended Length Endoscope
Regulation Number: 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: December 21, 2001
Received: December 26, 2001

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,

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

510(k) Number (if known): K 014250

Device Name: 7 mm Extended Length Endoscope

Indications For Use:

The 7 mm Extended Length Endoscope is indicated for visualization of a surgical cavity and dissection in endoscopic procedures and other minimally invasive surgical procedures allowing access for vessel harvesting, and is primarily indicated for patients undergoing endoscopic vessel harvesting for arterial bypass. It is indicated for patients requiring endoscopic tissue separation/vessel harvesting of the extraperitoneal or subcutaneous extremity and thoracic space. Extremity procedures include tissue dissection 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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

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

510(k) Number K014250