3/3/99

510(k) SUMMARY

K983-75

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Submitter's Name: Guidant Corporation
Advanced Cardiovascular Systems, Inc.
Submitter's Address: 3200 Lakeside Drive
Santa Clara, CA 95052
Telephone: 408-235-3000
Fax: 408-235-3743
Contact Person: Sandra Sundell

Date Prepared: September 1, 1998

Device Trade Name: Guidant MEGALINK™ Biliary Stent

Device Common Name: Biliary stent

Device Classification Name: Biliary Catheter

Device Classification: Class II

Summary of Substantial Equivalence:

The design, materials, method of delivery and intended use features of the Guidant MEGALINK™ Biliary Stent are substantially equivalent with regard to these features in the predicate device, the JJIS PALMAZ™ balloon-expandable Stent for the Biliary System (K905720 and K911581).

Device Description:

The Guidant MEGALINK™ Biliary Stent is a balloon-expandable stent designed to be placed percutaneously into the common bile duct and intended to treat malignant strictures in the biliary tree. The stent is fabricated from a single piece of 316L medical grade stainless steel tubing. The Guidant MEGALINK™ Biliary Stent is designed to be hand crimped onto a PTA balloon delivery catheter and expanded by balloon inflation. Two crimping 0.87 mm (0.035") and 0.35mm (0.014") are included to provide inner member support of the delivery catheter during stent crimping. Once the Guidant MEGALINK™ Biliary Stent is mounted onto the PTA balloon delivery catheter it is intended to be delivered and deployed in the biliary tree.

Intended Use:

The Guidant MEGALINK™ Biliary Stent is indicated for palliation of malignant strictures in the biliary tree.

Technological Characteristics:

The Guidant MEGALINK™ Biliary Stent incorporates similar design, components, method of deployment, materials and intended use of the predicate device, the JJIS PALMAZ™ balloon-expandable Stent for the Biliary System (K905720 and K911581). The Guidant MEGALINK™ Biliary Stent is provided in a range of expanded lengths from 18 to 38 mm and in a range of expanded diameters from 6 to 10 mm.

Performance Data:

The safety and effectiveness of the Guidant MEGALINK™ Biliary Stent has been demonstrated through data collected from nonclinical bench tests and analyses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 3 1999

Ms. Sandra Sundell
Senior Regulatory Affairs Coordinator
Guidant Corporation
P.O. Box 58167
Santa Clara, California 95052

Re: K983075
Guidant MEGALINK™ Biliary Stent
Regulatory Class: II
21 CFR 876.5010
Product Code: 78 FGE
Dated: December 14, 1998
Received: December 15, 1998

Dear Ms. Sundell:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. 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.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

> The safety and effectiveness of this device for use in the vascular system have not been established.

Furthermore, the indication for biliary use must be prominently displayed in all labeling, including pouch, box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. *Please note:* this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Susan Alpert, Ph.D., M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known):

Device Name: Guidant MEGALINK™ Biliary Stent

Indications for Use:
The Guidant MEGALINK™ Biliary Stent is indicated for the palliation of malignant strictures in the biliary tree.

(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)**

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K983075 | S001