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JUN 1 5 2001

510(k) SUMMARY

The 510(k) Summary is submitted in accordance with 21 CFR Part 807, Section 807.92

Submitter's Name: Guidant Corporation
Advanced Cardiovascular Systems, Inc.

Submitter's Address: 3200 Lakeside Drive
Santa Clara, CA 95052

Telephone: 408/845-1419
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Contact Person: Curtis Truesdale

Date Prepared: May 15, 2001

Device Trade Name: OMNILINK™ .035 Biliary Stent System

Device Common Name: Biliary Stent

Device Classification Name: Biliary Catheter

Device Classification: Class II

Summary of Substantial Equivalence:

The OMNILINK™ .035 Biliary Stent System consisting of 18, 28, 38, 58 mm length stents and 80 cm & 135 delivery catheter lengths is substantially equivalent to the OTW MEGALINK™ SDS Biliary Stent System with the 18, 28, 38, mm length stents and 75cm & 135 cm delivery catheter lengths (K992319, K000550, and K001222) with respect to design, materials, method of delivery and intended use.

Device Description:

The OMNILINK™ .035 Biliary Stent System is comprised of a stainless steel, balloon-expandable stent pre-mounted onto an over-the-wire (OTW) delivery catheter. This system is designed for percutaneous placement in the common bile duct and intended to treat malignant strictures in the biliary tree.

The OMNILINK™ Biliary Stent consists of a dual stent design, fabricated from a single piece of 316L medical grade stainless steel tubing. The delivery catheter's central lumen is designed to permit the use of a 0.035" guide wire to facilitate advancement of the catheter to and through the stricture to be dilated. Once the delivery system is placed in the desired location, the stent expands upon inflating the balloon with contrast medium.

The balloon provides an expandable segment of known diameter and length at specific pressures. In addition, the balloon has two radiopaque markers to aid in stent positioning. The stent is designed to remain in the biliary duct as a permanent implant.

The OMNILINK™ .035 Biliary Stent System consists of 18 mm, 28 mm, 38 mm, and 58 mm length stents premounted onto either an 80 cm or 135 cm length delivery catheter with balloons ranging from 5.0-10 mm in diameters. The stent and delivery system are supplied sterile and intended for single use only.

Intended Use:

The OMNILINK™ .035 Biliary Stent System is indicated for palliation of malignant strictures in the biliary tree.

Technological Characteristics:

Comparisons of the subject and predicate device show that technological characteristics such as materials, biocompatibility, mode of operation, performance properties, sterilization and packaging are substantially equivalent to the currently marketed predicate device, the OTW MEGALINK™ SDS Biliary Stent System.

Performance Data:

The safety and effectiveness of the OMNILINK™ .035 Biliary Stent System has been demonstrated through data collected from *in vitro* bench tests and analyses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 5 2001

Mr. Curtis Truesdale
Regulatory Affairs Coordinator
Guidant Corporation
P.O. Box 58167
Santa Clara, California 95052-8167

Re: K011506
OMNILINK™ .035 Biliary Stent System
Regulatory Class: II
21 CFR §876.5010
Product Code: 78 FGE
Dated: May 15, 2001
Received: May 16, 2001

Dear Mr. Truesdale:

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,

Bernard E. Statland, M.D., Ph.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K011506

Device Name: OMNILINK™ .035 Biliary Stent System

FDA's Statement of the Indications For Use for device:

The OMNILINK™ .035 Biliary Stent System is indicated for use in the palliation of malignant neoplasms in the biliary tree.

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

Colin M Pollard
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K011506