GUIDANT

510(k) SUMMARY

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

Submitter's Name: Guidant Corporation

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

Telephone: 650-470-6372
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Contact Person: Michelle Grossman

Date Prepared: August 14, 2003

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 design, materials, method of delivery and intended use features of the subject device are substantial equivalent with regard to these features in the predicate device, the OMNILINK® .035 Biliary Stent System (K011506, cleared June 15, 2001). The new sizes will be marketed as part of the OMNILINK® .035 Biliary Stent System product line.

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 subject OMNILINK® .035 Biliary Stent System consists of additional stent sizes of 4.0, 5.0, 6.0, 7.0mm stent diameter, 12 and 16mm stent lengths, and 4.0mm stent diameter x 18mm stent length. 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, OMNILINK® .035 Biliary Stent System.

Performance Data:

The safety and effectiveness of the subject 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

OCT 2 3 2003

Ms. Michelle Grossman
Regulatory Affairs
Guidant Corporation
3200 Lakeside Drive
SANTA CLARA CA 95054-2807

Re: K032530
Trade/Device Name: OMNILINK® .035 Biliary Stent System
Regulation Number: 21 CFR §876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: 78 FGE
Dated: September 23, 2003
Received: September 24, 2003

Dear Ms. Grossman:

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 (PMA), it may be subject to 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.

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 Section 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 Part 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 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,

Daniel G. Schultz, M.D.
Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K032530

Device Name: OMNILINK® .035 Biliary Stent System

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

OMNILINK® .035 Biliary Stent System is intended as a palliative treatment of malignant neoplasms in the biliary tree.

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

David A. Kessman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K032530