MAY 1 7 2000

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: 408-845-3995
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Contact Person: Margaret Anderson
Date Prepared: April 14, 2000

Device Trade Name: OTW MEGALINK™ SDS 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 OTW MEGALINK™ SDS Biliary Stent System with the 18, 28, and 38 mm stent lengths and 135 cm delivery catheter length are substantially equivalent with regard to these features in the predicate device, the OTW MEGALINK™ SDS Biliary Stent System with the 18, 28, and 38 mm stent lengths and 75 cm length delivery catheter.

Device Description:

The OTW MEGALINK™ SDS Biliary Stent System is a balloon-expandable stent pre-mounted onto an over-the-wire (OTW) delivery catheter 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 stent is pre-mounted onto an OTW delivery catheter with an integrated shaft system and an XCELON™ balloon bonded at the distal end. The shaft has a coaxial dual lumen extending the entire length of the catheter. The outer lumen provides for inflation of the balloon with contrast medium. The central lumen permits use of a guide wire to facilitate advancement of the catheter to and through the stricture to be dilated.

The balloon has 2 radiopaque markers to aid in positioning the balloon in the biliary duct and is designed to provide an expandable segment of known diameter and length at specific pressures.

The proximal end has a dual arm adapter, one for the guide wire lumen and the other for access to the inflation lumen. The adapter arm used to access the inflation lumen is designed with a luer-lock fitting for connection to an inflation device.

The OTW MEGALINK™ SDS Biliary Stent System consists of an 18, 28, or 38 mm length stent pre-mounted onto a 135 cm length delivery catheter with balloon diameters ranging from 6 – 10 mm depending on stent length. The OTW MEGALINK™ SDS Biliary Stent System is intended to be delivered and deployed in the biliary tree.

Intended Use:

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

Technological Characteristics:

Comparisons of the new and predicate devices show that technological characteristics such as materials, biocompatibility, performance properties, sterilization and packaging are substantially equivalent to the currently marketed predicate devices. The design modification of the new biliary stent system compared to that of the predicate biliary stent system is the length of the delivery catheter and the additional proximal marker.

Performance Data:

The safety and effectiveness of the OTW MEGALINK™ SDS 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

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Ms. Margaret Anderson
Regulatory Affairs Coordinator
Guidant Corporation, Advanced Cardiovascular Systems, Inc.
P.O. Box 58167
Santa Clara, California 95052-8167

Re: K001222
OTW MEGALINK™ SDS Biliary Stent System,
135 cm Length Delivery Catheter
Regulatory Class: II
21 CFR 876.5010
Product Code: 78 FGE
Dated: April 14, 2000
Received: April 17, 2000

Dear Ms. Anderson:

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,

Heather S Rosecrans /for

David W. Feigal, Jr., M.D., M.P.H.
Acting Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K001222

Device Name: OTW MEGALINK™ SDS Biliary Stent System

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

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

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

(Division Sign-Off)
Division of [illegible] Ophthalmic, ENT,
and Radiological [illegible]
510(k) Number K001222