GUIDANT NOV 1 0 2003

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

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Contact Person: Kelly Pike

Date Prepared: October 22, 2003

Device Trade Name: ABSOLUTE™ .035 Biliary Self-Expanding Stent System

Device Common Name: Biliary Stent

Device Classification Name: Biliary Catheter

Device Classification: Class II

Summary of Substantial Equivalence:

The ABSOLUTE™ .035 Biliary Self-Expanding Stent System is substantially equivalent to:

- DYNALINK™ .035 Biliary Self-Expanding Stent System (K014184)
- SMART Therapeutics, Neuroform Microdelivery StentSystem (H020002)
- Cordis, SMART Control Nitinol Biliary Stent (K021898)
- AngioDynamics AngioStent Biliary Stent System (K982346)
- Cordis, SMART Nitinol Stent (K020052)
- Advantec Vascular, DuraMax Biliary Stent System (K030638)

Device Description:

The ABSOLUTE™ Biliary Self-Expanding Stent System is comprised of the ABSOLUTE™ stent pre-mounted on an over-the-wire delivery system. The delivery catheter consists of three coaxial members (an inner member, a retractable outer member, and an outer, outer member), a guide wire lumen, a distal soft tip and a proximal handle with retraction and locking features. The distal section of the outer member constrains the stent on the inner member. Deployment of the ABSOLUTE™ stent occurs when the outer member is retracted by activating the retraction features in the handle.

Intended Use:

The ABSOLUTE™ .035 Biliary Self-Expanding Stent System is intended for palliation of malignant strictures in the biliary tree.

Technological Characteristics:

The design modifications incorporated into the ABSOLUTE™ .035 Biliary Self-Expanding Stent System include radiopaque markers at the ends of the stent, new stent lengths and a modified delivery system that has an outer jacket, a new handle design and delivery system lengths.

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.

Performance Data:

The results of the *in vitro* bench tests and analyses demonstrated the safety and effectiveness of the ABSOLUTE™ .035 Biliary Self-Expanding Stent System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 0 2003

Mr. Kelly Pike
Regulatory Affairs
Guidant Corporation
3200 Lakeside Drive
Santa Clara, CA 95054

Re: K033393
Trade/Device Name: Guidant ABSOLUTE™ .035 Biliary Self Expanding Stent
Regulation Number: 21 CFR §876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: 78 FGE
Dated: October 22, 2003
Received: October 23, 2003

Dear Mr. Pike:

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). 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 described above is added to your labeling.

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), please contact the Office of Compliance at (301) 594-4616. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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: K033393

Device Name: Guidant ABSOLUTE™ .035 Biliary Self Expanding Stent

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

The ABSOLUTE™ .035 Biliary Self Expanding Stent is intended for palliation of malignant strictures in the biliary tree.

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K033393