K053454
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GUIDANT

MAR 6 2006

## Appendix B

## 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<br>Santa Clara, CA 95054 |
| Telephone: | 951-914-2771 |
| Fax: | 951-914-2145 |
| Contact Person: | Keith Krohn |
| Date Prepared: | December 8, 2005 |
| Device Trade Name: | RX HERCULINK® ELITE™ Biliary Stent System |
| Device Common Name: | Biliary Stent |
| Device Classification Name: | Biliary Catheter |
| Device Classification: | Class II |

**Summary of Substantial Equivalence:**

The RX HERCULINK® ELITE™ Biliary Stent System is substantially equivalent to: HERCULINK® PLUS Biliary Stent System (K010684, cleared 4/12/2001); and Cordis Palmaz BLUE .018 Transhepatic Biliary Stent System, (K040413, cleared 6/21/2004)

**Device Description:**

The RX HERCULINK ELITE Biliary Stent System features a balloon expandable stent composed of L605 Cobalt Chromium. The stent design is based upon a series of zig-zagging rings with multiple links per ring. The stent is available in 12mm, 15mm, and 18mm lengths. The delivery system is a rapid exchange, co-axial design with a balloon at the distal end. The proximal lumen provides for inflation of the balloon with contrast medium. The central distal lumen permits use of a guidewire to facilitate advancement of the catheter to and through the stricture to be dilated. The balloon has radiopaque marker(s) to aid in positioning the balloon in the stricture, and is designed to provide an expandable segment of known diameter and length at specified pressures. Markers located on the proximal outer shaft help the physician gauge the dilatation catheter position relative to the guiding catheter tip.

**Intended Use:**

The RX HERCULINK ELITE Biliary Stent System is intended for palliation of malignant strictures in the biliary tree.

**Performance Data:**

The results of the *in vitro* bench tests and analyses and biocompatibility testing demonstrated the safety and effectiveness of the RX HERCULINK ELITE Biliary Stent System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 6 2006

Mr. Keith Krohn
Manager, Regulatory Affairs
Guidant Corporation
26531 Ynez Road
TEMECULA CA 92591

Re: K053454
Trade/Device Name: Guidant HERCULINK® ELITE Biliary Stent System
Regulation Number: 21 CFR §876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: FGE
Dated: February 15, 2006
Received: February 17, 2006

Dear Mr. Krohn:

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,

for Miriam C. Provost

Donna-Bea Tillman, Ph.D., M.P.A.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K053454

Device Name: Guidant HERCULINK® ELITE Biliary Stent System

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

The Guidant HERCULINK® ELITE Biliary Stent System is intended for palliation of malignant strictures in the biliary tree.

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K053454

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