4/30/99

K991032

510(k) Summary

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

1.	Submitter's Name:	Guidant Corporation Advanced Cardiovascular Systems, Inc.
2.	Submitter's Address:	3200 Lakeside Drive Santa Clara, CA 95054
3.	Telephone:	408-235-4174
4.	Fax:	408-235-3743
5.	Contact Person:	Kobby Dankwah
6.	Date Prepared:	March 22, 1999
7.	Device Trade Name:	• Guidant MEGALINK™ Biliary Stent
8.	Device Common Name:	Biliary Stents
9.	Device Classification Name:	Biliary Catheter (78 FGE)
10.	Predicate Device:	Guidant MEGALINK™ Biliary Stent (K983075)

11. Device Description:

The Guidant MEGALINK™ Biliary Stent is a balloon-expandable stent designed to be placed percutaneously into the common bile duct and intended to treat malignant strictures in the biliary tree. The stent is for single use only and is a permanent implant. The Guidant MEGALINK™ Biliary Stent is fabricated from a single piece of 316L medical grade stainless steel tubing which conforms to ASTM Standard F-138-92 Grade 2.

The stent is comprised of a series of multiple rings with multiple links aligned along a common longitudinal axis. Each ring is approximately 2 mm long. The number of rings per stent is dependent upon the length of the stent, i.e., 8 rings for 18 mm, 13 rings for 28 mm and 17 rings for 38mm. The nominal strut thickness is .0060" and

the nominal strut width is .00575". The stent is balloon-expandable with an expansion range from 6 – 10 mm in diameter for the 58 mm length stents. The stent is designed to be hand crimped onto a percutaneous transluminal angioplasty (PTA) balloon catheter for stent delivery and deployment in the biliary tree. The stent may be post dilated with a PTA balloon catheter to ensure good stent deployment. The maximum post dilatation diameter for the 58 mm stent length is 11 mm.

12. Intended Use:

The Guidant MEAGALINK™ Biliary stent is indicated for the palliation of malignant strictures in the biliary tree.

13. Technological Characteristics:

Comparisons of the new and predicate devices show that technological characteristics such as materials, biocompatibility, performance properties, sterilization, and packaging are identical or substantially equivalent to the currently marketed predicate devices. The design modifications of the new guide wires compared to that of the predicate wire are the lengths of the stents.

14. Performance Data:

In vitro bench testing was performed to demonstrate that the Guidant MEGALINK Biliary stent met the acceptance criteria and performed similar to the predicate devices. The functional tests met product specifications.

15. Conclusions

Since the new stent length have the same intended use, technological characteristics, performance properties, identical sterilization and packaging, process and no new safety or effectiveness issues, the Guidant MEGALINK™ Biliary Stent (58 mm stent length) may be considered substantially equivalent to the predicate Guidant MEGALINK™ Biliary Stent (18 mm, 28 mm, and 38 mm stent length).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 30 1999

Mr. Kobby Dankwah
Manager, Regulatory Affairs
Guidant Corporation
P.O. Box 58167
Santa Clara, California 95052

Re: K991032
Guidant MEGALINK™ Biliary Stent, 58 mm Length
Dated: March 26, 1999
Received: March 29, 1999
Regulatory Class: II
21 CFR 876.5010
Product Code: 78 FGE

Dear Mr. Dankwah:

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,

Susan Alpert, Ph.D., M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K991032

Device Name: Guidant MEGALINK™ Biliary Stent, 58 mm Length

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

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

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K991032

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