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K982876

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APPENDIX VI
510(k) SUMMARY

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This 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.
Submitter's Address: 3200 Lakeside Drive
Santa Clara, CA 95054
Telephone: 408-235-3995
Fax: 408-235-3743
Contact Person: Susan Silavin, Ph.D.
Date Prepared: August 13, 1998

2. Device Trade Name: HI-TORQUE STEELCORE™ 18
Guide Wire

Device Common Name: Guide Wire

Device Classification Name: Catheter Guide Wire (74DQX)

3. Predicate Devices:
ACS HI-TORQUE IRON MAN™ Guide Wire (K963702, approved January 22, 1997)
Medi-tech Platinum Plus™ Guide Wire (K945379, approved June 5, 1995)

4. Device Description:

The HI-TORQUE STEELCORE™ 18 Guide Wire is a steerable guide wire with a nominal diameter of 0.018 inches and three lengths: a 130 cm, a 190 cm and a 300 cm exchange length.

5. Intended Use:

The HI-TORQUE STEELCORE™ 18 Guide Wire is intended to facilitate the placement and exchange of diagnostic and therapeutic devices during intravascular procedures. It is not intended for use in the cerebral vasculature.

6. Technological Characteristics:

Comparisons of the new and predicate devices show that technological characteristics such as materials, biocompatibility, performance properties (see below), sterilization, and packaging are identical or substantially equivalent to the currently marketed predicate devices.

7. Performance Data:

Bench testing was performed to demonstrate that the HI-TORQUE STEELCORE™ 18 Guide Wire met the acceptance criteria and performed similar to the predicate guide wires. The following tests were performed:

- Distal Tip Pull Test
- Turns-to-Failure Test
- Rotational Accuracy Test
- Tip Flexibility Test

The results from the bench tests showed that the new HI-TORQUE STEELCORE™ 18 Guide Wire met acceptance criteria and performed in a manner equivalent to the predicate guide wires. No new safety or effectiveness issues were raised during the testing program.

8. Conclusions:

Since the new guide wire has the same intended use, similar design and technological characteristics, equivalent performance properties, identical sterilization and packaging, and no new safety or effectiveness issues, the HI-TORQUE STEELCORE™ 18 Guide Wire may be considered substantially equivalent to the predicates, ACS Hi-Torque IRON MAN™ and the Medi-tech Platinum Plus™ Guide Wires.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

NOV 10 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Susan Silavin, Ph.D.
Senior Regulatory Affairs Coordinator
Guidant Corporation
3200 Lakeside Drive
Santa Clara, CA 95054

Re: K982876

Trade Name: HI-TORQUE STEELCORE™ 18 Guide Wire
Regulatory Class: II
Product Code: DQX
Dated: August 13, 1998
Received: August 14, 1998

Dear Dr. Silavin:

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. 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.

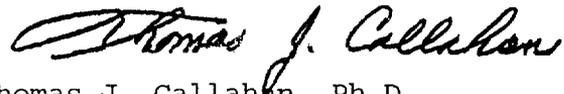
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 pre-market 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.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. 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" (21CFR 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,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory
And Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

