K981381

JUL 15 1998

APPENDIX V

510(k) SUMMARY

510(k) SUMMARY

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: Margaret Anderson
   Date Prepared: April 15, 1998

2. Device Trade Name: HI-TORQUE CROSS-IT™ Guide Wire with HYDROCOAT™ Hydrophilic Coating

   Device Common Name: Guide Wire

   Device Classification Name: Catheter Guide Wire (74DQX)

3. Predicate Device: HI-TORQUE TRAVERSE® Guide Wire with HYDROCOAT™Hydrophilic Coating

4. Device Description:

   The ACS HI-TORQUE CROSS-IT™ Guide Wire with HYDROCOAT™ Hydrophilic Coating is a steerable guide wires with a nominal diameter of 014" and available in:
   175 cm and 190 cm extendable lengths and a 300 cm exchange length. The proximal end of the 190 cm models are tapered to fit into the hypotube portion of the ACS DOC® Guide Wire Extension. The wire is constructed from a stainless steel core wire. The distal end of the guide wire has a radiopaque tip that are available either as a straight or as a preshaped J. The hydrophilic coating is applied to the distal portion of the wire guide wire. The proximal section of the guide wire is coated with polytetrafluoroethylene.

5. Intended Use:

   To facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA).

6. 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 feature that distinguishes the new guide wires from that of the predicate wires is the tapered distal coil.

7. Performance Data:

Bench testing was performed to demonstrate that the ACS HI-TORQUE CROSS-IT™ Guide Wire with HYDROCOAT™ Hydrophilic Coating met the acceptance criteria and performed similar to the predicate HI-TORQUE TRAVERSE® Guide Wire with HYDROCOAT™ Hydrophilic Coating. The following tests were performed: Distal Tip Pull Test, Distal Tip Turns-to-Failure Test, Rotational Accuracy Test and Tip Flexibility Test.

The results from the bench tests showed that the new ACS HI-TORQUE CROSS-IT™ Guide Wire with HYDROCOAT™ Hydrophilic Coating met the acceptance criteria and performed in a manner equivalent the predicate ACS HI-TORQUE TRAVERSE® Guide Wire with HYDROCOAT™ Hydrophilic Coating. No new safety or effectiveness issues were raised during the testing program.

8. Conclusions:

Since the new guide wires have the same intended use, technological characteristics, performance properties, identical sterilization and packaging, and no new safety or effectiveness issues, the ACS HI-TORQUE CROSS-IT™ Guide Wire with HYDROCOAT™ Hydrophilic Coating may be considered substantially equivalent to the predicate ACS HI-TORQUE TRAVERSE® Guide Wires with HYDROCOAT™ Hydrophilic Coating.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 15 1998

Ms. Margaret Anderson
Guidant Corporation
3200 Lakeside Drive
P.O. Box 58167
Santa Clara, CA 95052-8167

Re: K981381
ACS HI-TORQUE CROSS-IT™ Guide Wire with HYDROCOAT™ Coating
Regulatory Class: II (two)
Product Code: 74 DQX
Dated: April 15, 1998
Received: April 16, 1998

Dear Mr. Anderson:

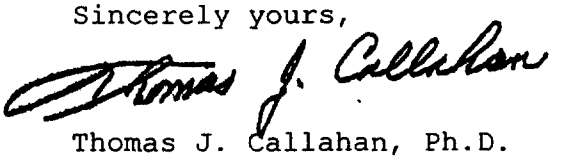
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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. 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 (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.

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) 594-4648. 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,



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

Enclosure

Indications for Use Statement

510(k) Number (if known):

Device Name:

ACS HI-TORQUE CROSS-IT™ Guide Wire with HYDROCOAT™ Hydrophilic Coating

Indications for Use:

To facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA).

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K981381

Prescription Use ✓ **OR** **Over-The-Counter** _____
(Per 21 CFR 801.109) **(Optional Format 1-1-96)**