3/23/99

K983346

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: September 21, 1998

2. Device Trade Name: HYDROCORE™ Guide Wire

   Device Common Name: Guide Wire

   Device Classification Name: Catheter Guide Wire (74DQX)

3. Predicate Device: ACS HI-TORQUE WHOLEY SUPRA CORE™ Guide Wire
   Terumo® Radifocus® Glidewire® Guide Wire

4. Device Description:

   The HYDROCORE™ Guide Wire is a 150 cm length guide wire is available in nominal diameters of 0.025", 0.032", 0.035" and 0.038", with shaft stiffness variations of: soft, standard, and extra stiff. The wires come in straight and angled tip configurations. The wire is constructed from a stainless steel core wire that is encased in a urethane resin and surfaced with a hydrophilic coating. The urethane casing contains radiopaque properties.

5. Intended Use:

   The HYDROCORE™ Guide Wire is intended to facilitate the placement of diagnostic and therapeutic devices during intravascular procedures.

6. Technological Characteristics:

   Comparisons of the new and predicate devices show that the technological characteristics such as design, materials, functional performance properties, 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 HYDROCORE™ Guide Wire met the acceptance criteria of the product specifications and performed similar to that of the predicate. The following bench tests were performed: tensile strength test, torque strength test, tip flexibility, torqueability and coating adhesion and integrity test.

The results from the bench tests showed that the new HYDROCORE™ Guide Wire met the acceptance criteria and performed in a manner equivalent the predicate device. No new safety or effectiveness issues were raised during the testing program.

8. Conclusions:

The new guide wire has a similar intended use, and has the same technological characteristics, performance properties, identical sterilization and packaging as those of the predicate devices. Furthermore, the results from the bench tests showed that no new safety or effectiveness issues were raised during the testing program. Therefore, the HYDROCORE™ Guide Wire may be considered substantially equivalent to the predicate ACS HI-TORQUE WHOLEY SUPRA CORE™ Guide Wire and the Terumo® Radifocus® Glidewire® Guide Wire.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 23 1999

Ms. Margaret Anderson
Regulatory Affairs Coordinator
Guidant Corporation
Vascular Intervention Group
3200 Lakeside Drive
Santa Clara, CA 95054

Re: K983346
Trade Name: HYDROCORE™ Guide Wire
Regulatory Class: II
Product Code: DQX
Dated: January 25, 1999
Received: January 26, 1999

Dear Ms. 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) 594-4586. 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

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:

HYDROCORE™ Guide Wire

Indications for Use:

The HYDROCORE™ Guide Wire is intended to facilitate the placement of diagnostic and therapeutic devices during intravascular procedures

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K983346