K-973494

510(k) SUMMARY

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

DEC 12 1997

1. Submitter's Name: Guidant Corporation
   Advanced Cardiovascular Systems, Inc.

   Submitter's Address: 3200 Lakeside Drive
   Santa Clara, CA 95052

   Telephone: 408-235-3995
   Fax: 408-235-3743
   Contact Person: Margaret Anderson
   Date Prepared: September 13, 1997

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

   ACS HI-TORQUE BALANCE MIDDLEWEIGHT™ Guide Wire with HYDROCOAT™ Hydrophilic Coating

   Device Common Name: Guide Wire

   Device Classification Name: Catheter Guide Wire (74DQX)

3. Predicate Device: HI-TORQUE BALANCE™ Guide Wire (K925381, approved February 12, 1993)

   ACS HI-TORQUE BALANCE MIDDLEWEIGHT™ Guide Wire (K971815, approved July 9, 1997)

   ChoICE™ PT Plus Guide Wire (K950216, approved June 22, 1995)

4. Device Description:

The HI-TORQUE BALANCE® Guide Wire with HYDROCOAT™ Hydrophilic Coating and the ACS HI-TORQUE BALANCE MIDDLEWEIGHT™ Guide Wire with HYDROCOAT™ Hydrophilic Coating are steerable guide wires with a nominal diameters of 0.014″ and two lengths: a 190 cm extendable length 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 (K902755, approved September 4, 1990).

The wires are constructed from a stainless steel proximal shaft and a distal superelastic ELASTINITE® Shaft for flexibility and performance. The distal end of this guide wires have radiopaque tips that are available either as a straight, shapeable configuration or as a preshaped J configuration. The guide wires have proximal markers at 90 and 100 cm

from the distal tip. The hydrophilic coating is applied to the distal portion of the wire guide wire. The proximal shaft of the guide wire is coated with polytetrafluoroethylene.

5. Intended Use:

The HI-TORQUE BALANCE® Guide Wire with HYDROCOAT™ Hydrophilic Coating and the ACS HI-TORQUE BALANCE MIDDLEWEIGHT™ Guide Wire with HYDROCOAT™ Hydrophilic Coating have the following intended uses:

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

- The wire is also intended to facilitate the placement of equipment such as atherectomy, IVUS and compatible stent devices during other diagnostic and therapeutic intravascular procedures.

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 device. The design feature that distinguish the new guide wire from that of the predicate wire is the new hydrophilic coating.

7. Performance Data:

Bench testing was performed to demonstrate that the HI-TORQUE BALANCE® Guide Wire with HYDROCOAT™ Hydrophilic Coating met the acceptance criteria and performed similar to the predicate HI-TORQUE BALANCE® Guide Wire. The following tests were performed:

- Accelerated Aging
- Distal Tip Pull Test
- Distal Tip Turns-to-Failure Test
- Rotational Accuracy Test
- Tip Flexibility Test
- Hypotube Junction Pull Test
- Hypotube Junction Maximum Torque test
- Coating Adherence/Integrity

In vivo animal testing in a canine model with healthy coronary arteries was performed to demonstrate performance properties of the HI-TORQUE BALANCE® Guide Wire with HYDROCOAT™ Hydrophilic Coating and the ACS HI-TORQUE BALANCE MIDDLEWEIGHT™ Guide Wire with HYDROCOAT™ Hydrophilic Coating in comparison to the predicate guide wire. The results showed that the new wires performed in an equivalent manner to the predicate devices.

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

8. Conclusions:

Since the new guide wires have 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 BALANCE® Guide Wire with HYDROCOAT™ Hydrophilic Coating and the ACS HI-TORQUE BALANCE MIDDLEWEIGHT™ Guide Wire with HYDROCOAT™ Hydrophilic Coating may be considered substantially equivalent to the predicate HI-TORQUE BALANCE® Guide Wire and the ACS HI-TORQUE BALANCE MIDDLEWEIGHT™ Guide Wire respectively.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Rockville MD 20857

DEC 12 1997

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

Re: K973494
HI-TORQUE BALANCE® Guide Wire with HYDROCOAT™
Hydrophilic Coating
Regulatory Class: II (two)
Product Code: DQX
Dated: September 13, 1997
Received: September 15, 1997

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 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/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: HI-TORQUE BALANCE™ Guide Wire with HYDROCOAT™ Hydrophilic Coating

ACS HI-TORQUE BALANCE MIDDLEWEIGHT™ Guide Wire with HYDROCOAT™ Hydrophilic Coating

Indications for Use:

~~The ACS HI-TORQUE BALANCE MIDDLEWEIGHT™ Guide Wire is a steerable wire intended~~ to facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). The wire is also intended to facilitate the placement of equipment such as atherectomy, IVUS and compatible stent devices during other diagnostic and therapeutic intravascular procedures.

ma 1/6/98

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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

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