

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. MAR 13 1998
 Submitter's Address: 3200 Lakeside Drive
 Santa Clara, CA 95052
 Telephone: 408-235-3995
 Fax: 408-235-3743
 Contact Person: Margaret Anderson
 Date Prepared: December 19, 1997

2. Device Trade Name:
- HI-TORQUE FLOPPY® Guide Wire with HYDROCOAT™ Hydrophilic Coating
 - HI-TORQUE STANDARD® Guide Wire with HYDROCOAT™ Hydrophilic Coating
 - HI-TORQUE INTERMEDIATE® Guide Wire with HYDROCOAT™ Hydrophilic Coating
 - HI-TORQUE APPROACH® Guide Wire with HYDROCOAT™ Hydrophilic Coating
 - HI-TORQUE FLOPPY II® Guide Wire with HYDROCOAT™ Hydrophilic Coating
 - HI-TORQUE TRAVERSE® Guide Wire with HYDROCOAT™ Hydrophilic Coating
 - ACS HI-TORQUE EXTRA S'PORT™ Guide Wire with HYDROCOAT™ Hydrophilic Coating
 - HI-TORQUE FLOPPY® EXTRA SUPPORT Guide Wire with HYDROCOAT™ Hydrophilic Coating
 - HI-TORQUE FLOPPY II ® EXTRA SUPPORT Guide Wire with HYDROCOAT™ Hydrophilic Coating
 - ACS HI-TORQUE IRON MAN® Guide Wire with HYDROCOAT™ Hydrophilic Coating

Device Common Name: Guide Wire

Device Classification Name: Catheter Guide Wire (74DQX)

3. Predicate Device:

- HI-TORQUE FLOPPY® Guide Wire with MICROGLIDE® Coating
- HI-TORQUE STANDARD® Guide Wire with MICROGLIDE® Coating
- HI-TORQUE INTERMEDIATE® Guide Wire with MICROGLIDE® Coating
- HI-TORQUE APPROACH® Guide Wire with MICROGLIDE® Coating
- HI-TORQUE FLOPPY II® Guide Wire with MICROGLIDE® Coating
- HI-TORQUE TRAVERSE® Guide Wire with MICROGLIDE® Coating
- ACS HI-TORQUE EXTRA S'PORT™ Guide Wire with MICROGLIDE® Coating
- HI-TORQUE FLOPPY® EXTRA SUPPORT Guide Wire with MICROGLIDE® Coating
- HI-TORQUE FLOPPY II® EXTRA SUPPORT Guide Wire with MICROGLIDE® Coating
- ACS HI-TORQUE IRON MAN® Guide Wire with MICROGLIDE® Coating
- ChoICE™ PT Plus Guide Wire

4. Device Description:

The HI-TORQUE Guide Wires with HYDROCOAT™ Hydrophilic Coating are steerable guide wires with a nominal diameters of .010", .014" and .018" and available in 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. The wires are constructed from a stainless steel core wire. The distal end of this guide wires have radiopaque tips that are available either as a straight, shapeable configuration 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:

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 ACS HI-TORQUE EXTRA S'PORT™ Guide Wire with HYDROCOAT™ Hydrophilic Coating and the ACS HI-TORQUE IRON MAN™ Guide Wire with HYDROCOAT™ Hydrophilic Coating are 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, 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 new hydrophilic coating.

7. Performance Data:

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

- Accelerated Aging
- Distal Tip Pull Test
- Distal Tip Turns-to-Failure Test
- Rotational Accuracy Test
- Tip Flexibility Test
- Coating Adherence/Integrity

The results from the bench tests showed that the new ACS HI-TORQUE® Guide Wires with HYDROCOAT™ Hydrophilic Coating met the acceptance criteria and performed in a manner equivalent to the predicate ACS HI-TORQUE® Guide Wire with MICROGLIDE® Coating and the ChoICE™ PT Plus 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, design and technological characteristics, equivalent performance properties, identical sterilization and packaging, and no new safety or effectiveness issues, the ACS HI-TORQUE® Guide Wires with HYDROCOAT™ Hydrophilic Coating may be considered substantially equivalent to the predicate ACS HI-TORQUE® Guide Wires with MICROGLIDE® Coating. Additionally, the new guide wires performed substantially equivalent with regards to coating adhesion integrity to the ChoICE™ PT Plus Guide Wire therefore, we conclude the new guide wire may be considered substantially equivalent to the predicate devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 13 1998

Ms. Margaret Anderson
Guidant Corporation
3200 Lakeside Drive
Santa Clara, CA 95054

Re: K974773
HI-TORQUE® Guide Wires with HYDROCOAT™ Hydrophilic Coating
Regulatory Class: II (two)
Product Code: 74 DQX
Dated: December 19, 1997
Received: December 22, 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.

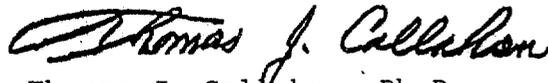
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

Page 2 - Ms. Margaret Anderson

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 FLOPPY® Guide Wire with HYDROCOAT™ Hydrophilic Coating
- HI-TORQUE STANDARD® Guide Wire with HYDROCOAT™ Hydrophilic Coating
- HI-TORQUE INTERMEDIATE® Guide Wire with HYDROCOAT™ Hydrophilic Coating
- HI-TORQUE APPROACH® Guide Wire with HYDROCOAT™ Hydrophilic Coating
- HI-TORQUE FLOPPY II® Guide Wire with HYDROCOAT™ Hydrophilic Coating
- HI-TORQUE TRAVERSE® Guide Wire with HYDROCOAT™ Hydrophilic Coating
- ACS HI-TORQUE EXTRA S'PORT™ Guide Wire with HYDROCOAT™ Hydrophilic Coating
- HI-TORQUE FLOPPY® EXTRA SUPPORT and HI-TORQUE FLOPPY II® EXTRA SUPPORT Guide Wire with HYDROCOAT™ Hydrophilic Coating
- ACS HI-TORQUE IRON MAN® Guide Wire with HYDROCOAT™ Hydrophilic Coating

Indications for Use:

- Facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA).
- The ACS HI-TORQUE EXTRA S'PORT™ Guide Wire with HYDROCOAT™ Hydrophilic Coating and the ACS HI-TORQUE IRON MAN™ Guide Wire with HYDROCOAT™ Hydrophilic Coating are also intended to facilitate the placement of equipment such as atherectomy and compatible stent devices during other diagnostic and therapeutic 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)

Tu A R
(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number 1974773