

APR 24 1998

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 95052
Telephone: 408-235-3480
Fax: 408-235-3743
Contact Person: David Kolesar
Date Prepared: January 26, 1998

- 2. Device Trade Name: ACS HI-TORQUE® SUPER S'PORT™ Guide Wire with
HYDROCOAT™ Hydrophilic Coating ACS HI-TORQUE®

Device Common Name: Guide Wire

Device Classification Name: Catheter Guide Wire (74DQX)

- 3. Predicate Device: ACS HI-TORQUE® IRON MAN™ Guide Wire (K963702)

ACS HI-TORQUE® BALANCE™ Guide Wire with
HYDROCOAT™ Hydrophilic Coating (K973494)

- 4. Device Description:

The ACS HI-TORQUE® SUPER S'PORT™ Guide Wire with HYDROCOAT™ Hydrophilic Coating is a steerable guide wire 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, September 4, 1990).

The ACS HI-TORQUE® SUPER S'PORT™ Guide Wire with HYDROCOAT™ Hydrophilic Coating has a radiopaque tip and is are available with either a straight tip configuration, which allows the physician to shape the guide wire tip in a preferred shape, or a pre-shaped "J" tip configuration, which allows the physician the convenience using a guide wire with the tip pre-shaped.

The hydrophilic coating is intended to facilitate wire movement within 0.014" diameter devices. The proximal shaft of the ACS HI-TORQUE® SUPER S'PORT™ Guide Wire with HYDROCOAT™ Hydrophilic Coating is coated with polytetrafluoroethylene (PTFE).

5. Intended Use:

The the ACS HI-TORQUE® SUPER S'PORT™ 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 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

7. Performance Data:

Bench testing was performed to demonstrate that the the ACS HI-TORQUE® SUPER S'PORT™ Guide Wire with HYDROCOAT™ Hydrophilic Coating met the acceptance criteria and performed similar to the predicate ACS HI-TORQUE® IRON MAN™ 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
- Coating Adherence/Integrity

In vivo animal testing in a canine model with healthy coronary arteries was performed to demonstrate performance properties of the the ACS HI-TORQUE® SUPER S'PORT™ 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 the ACS HI-TORQUE® SUPER S'PORT™ Guide Wire with HYDROCOAT™ Hydrophilic Coating met acceptance criteria and performed in a manner equivalent the ACS HI-TORQUE® IRON MAN™ 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 the ACS HI-TORQUE® SUPER S'PORT™ Guide Wire with HYDROCOAT™ Hydrophilic Coating may be considered substantially equivalent to the ACS HI-TORQUE® IRON MAN™ Guide Wire.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. David Kolesar
Senior Regulatory Affairs Coordinator
Guidant Corporation
3200 Lakeside Drive
Santa Clara, CA 95052

Re: K980294
Trade Name: ACS HI-TORQUE® SUPER S'PORT™ Guide Wire with
Hydrocoat™ Hydrophilic Coating
Regulatory Class: II
Product Code: DQX
Dated: January 26, 1998
Received: January 27, 1998

Dear Mr. Kolesar:

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

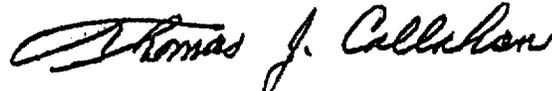
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concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation 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) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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

INDICATION FOR USE STATEMENT

DEVICE NAME:

ACS HI-TORQUE® SUPER S'PORT™ Guide Wire with Hydrocoat™ Hydrophilic Coating

INDICATIONS FOR USE:

The ACS HI-TORQUE® SUPER S'PORT™ Guide Wire with Hydrocoat™ Hydrophilic Coating is steerable wire intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA).

The ACS HI-TORQUE® SUPER S'PORT™ Guide Wire with Hydrocoat™ Hydrophilic Coating is also intended to facilitate the placement of equipment, such as atherectomy and stent devices, during other diagnostic and therapeutic intravascular procedures.

CONTRAINDICATIONS:

The ACS HI-TORQUE® SUPER S'PORT™ Guide Wire with Hydrocoat™ Hydrophilic Coating is not intended for use in the cerebral vasculature.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

M. Payne

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K980294

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter _____
(Optional Format 1-1-96)