K 971142

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: 26531 Ynez Road
   Temecula, CA 92591-4628
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   Contact Person: Wayne R. Hohman
   Date Prepared: June 5, 1997

AUG 25 1997

2. Device Trade Name: ACS HI-TORQUE ALL STAR™ 0.014" Guide Wire with Microglide® Coating
   Device Common Name: Guide Wire
   Device Classification Name: Catheter Guide Wire (74DQX)

3. Predicate Device: ACS HI-TORQUE EXTRA S'PORT™ 0.014" Guide Wire with Microglide® Coating (K950156, cleared April 5, 1995, and K942066, cleared July 18, 1994)

4. Device Description:

   The ACS HI-TORQUE ALL STAR™ 0.014" Guide Wire with Microglide® Coating is a steerable guide wire with a nominal diameter 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 is tapered to fit into the hypotube portion of the ACS DOC® Guide Wire Extension (K902755, cleared September 4, 1990). The proximal shaft of this guide wire is coated with polytetrafluoroethylene (PTFE) and the distal working end is coated with Microglide® Coating, a silicon based material. The distal end has a 3 cm, flexible, radiopaque tip that is provided either as a straight, shapeable configuration or as a preshaped J configuration. These guide wires have proximal markers at 90 and 100 cm from the distal tip.

   Two features distinguish the new guide wire from the predicate guide wire: the addition of a segment of tetrafluoroethylene (TFE) shrink tubing around the distal portion of the guide wire proximal to the 3 cm tip and a more flexible 3 cm tip.

5. Intended Use:

   The ACS HI-TORQUE ALL STAR™ 0.014" Guide Wire with Microglide® Coating has the following intended uses:

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

- To facilitate the placement of equipment such as compatible stent devices during other diagnostic or therapeutic intravascular procedures

The ACS HI-TORQUE ALL STAR™ 0.014" Guide Wire with Microglide® Coating has the following contraindications:

- Use in cerebral vasculature.

- Use with atherectomy devices.

NOTE: The predicate guide wire is indicated for use with atherectomy devices; the new guide wire is contraindicated for use with atherectomy devices.

6. Technological Characteristics:

Comparison of the new and predicate devices shows 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. Two design features distinguish the new guide wire: an added segment of tetrafluoroethylene (TFE) shrink tubing around the distal portion of the guide wire just proximal to the 3 cm tip and a more flexible 3 cm tip. The TFE shrink tubing provides a continuous working diameter of 0.014" in this distal portion of the guide wire. The decreased coefficient of friction of the TFE layer facilitates movement of the guide wire within 0.014" devices. The more flexible tip is designed to be more atraumatic in coronary vessels.

7. Performance Data:

Bench testing was performed to demonstrate that the ACS HI-TORQUE ALL STAR™ 0.014" Guide Wire with Microglide® Coating met acceptance criteria and performed similar to the predicate ACS HI-TORQUE EXTRA S'PORT™ 0.014" Guide Wire with Microglide® Coating. Four tests were performed as follows:

- Distal Tip Pull Test
- Distal Tip Turns-to-Failure Test
- Rotational Accuracy Test
- Tip Flexibility Test

In vivo animal testing in a canine model with healthy coronary arteries was performed to demonstrate performance properties of the ACS HI-TORQUE ALL STAR™ 0.014" Guide Wire in comparison to the predicate guide wire. The results showed that the ACS HI-TORQUE ALL STAR™ 0.014" Guide Wire performed in a manner equivalent to the ACS HI-TORQUE EXTRA S'PORT™ 0.014" Guide Wire.

The results from the four bench tests plus the animal testing showed that the new ACS HI-TORQUE ALL STAR™ Guide Wire met acceptance criteria and performed in a manner equivalent the predicate ACS HI-TORQUE EXTRA S'PORT™ 0.014" Guide Wire. No new safety or effectiveness issues were raised during the testing program.

8. Conclusions:

Since the new guide wire has the same intended use (minus the atherectomy indication), similar design and technological characteristics, no new materials, equivalent performance properties, identical sterilization and packaging, and no new safety or effectiveness issues, the ACS HI-TORQUE ALL STAR™ Guide Wire with Microglide® Coating may be considered substantially equivalent to the predicate ACS HI-TORQUE EXTRA S'PORT™ Guide Wire with Microglide® Coating.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

Mr. Wayne R. Hohman
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Guidant Corporation
Advanced Cardiovascular Systems
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Temecula, California 92591-4628

AUG 25 1997

Re: K972142
ACS HI-TORQUE ALL STAR™ 0.014" Guide Wire with Microglide® Coating
Regulatory Class: II (two)
Product Code: DQX
Dated: June 5, 1997
Received: June 6, 1997

Dear Mr. Hohman:

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): K972142

Device Name: ACS HI-TORQUE ALL STAR™ 0.014" Guide Wire with Microglide® Coating

Indications for Use:

- To facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA).
- To facilitate the placement of equipment such as compatible stent devices during other diagnostic or therapeutic intravascular procedures.

Contraindications:

- Use in cerebral vasculature.
- Use with atherectomy devices.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR over-the-counter _____
(Per 21 CFR 801.109)

(Optional Format 1-1-96)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K972142