

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: 408-235-3995
Fax: 408-235-3743
Contact Person: Margaret Anderson
Date Prepared: March 3, 1999

2. **Device Trade Name:** ACS HI-TORQUE WIGGLE™ Guide Wire with
 MICROGLIDE® Coating

Device Common Name: Guide Wire

Device Classification Name: Catheter Guide Wire (74DQX)

3. **Predicate Device:** ACS HI-TORQUE FLOPPY II® EXTRA
 SUPPORT Guide Wire with MICROGLIDE®
 Coating (K913353)

 ACS Angioscope Guide Wire (K883000)

4. **Device Description:**

The ACS HI-TORQUE WIGGLE™ Guide Wire with MICROGLIDE® Coating is a guide wire with a nominal diameter of 0.014" 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 wire is constructed from stainless steel, the distal end of this guide wire has a radiopaque tip that is available either as a straight, shapeable configuration or as a preshaped J. The distal end of the wire has sinusoidal waves manufactured approximately 4.5 cm - 6.5 cm from to the distal tip. The guide wire has proximal markers at 90 and 100 cm from the distal tip. MICROGLIDE® Coating is applied to the distal section of the guide wire, the proximal shaft is coated with polytetrafluoroethylene.

5. Intended Use:

The intended use of the ACS HI-TORQUE WIGGLE™ Guide Wire with MICROGLIDE® Coating is to facilitate the placement of the catheter by orienting the catheter tip during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA) and other interventional diagnostic or therapeutic procedures.

6. Technological Characteristics:

Comparisons of the Wiggle Guide Wire and predicate Hi-Torque Floppy II® Extra Support Guide Wire show that technological characteristics such as materials, biocompatibility, performance properties, sterilization, and packaging are identical or substantially equivalent to the predicate device. Similar in design to the Angioscope Guide Wire, the WIGGLE™ Guide Wire has a sinusoidal wave design manufactured in the distal tip section of the wire.

7. Performance Data:

Bench testing was performed to demonstrate that the ACS HI-TORQUE WIGGLE™ Guide Wire with MICROGLIDE® Coating met the acceptance criteria and performed similar to the predicate ACS HI-TORQUE FLOPPY II® EXTRA SUPPORT Guide Wire with MICROGLIDE® Coating. The following tests were performed: Distal Tip Pull Test, Distal Tip Turns-to-Failure Test, Rotational Accuracy Test, Tip Flexibility Test.

Additionally, *in vitro* heart model studies were performed to substantiate the intended use of the ACS HI-TORQUE WIGGLE™ Guide Wire. The results of the heart model study demonstrated that the new wire performs as intended.

The results from the bench tests showed that the new ACS HI-TORQUE WIGGLE™ Guide Wire with MICROGLIDE® Coating is substantially equivalent to the predicate wires and performs as intended. No new safety or effectiveness issues were raised during the testing program.

8. Conclusions:

The ACS HI-TORQUE WIGGLE™ Guide Wire has shown to have similar design and technological characteristics, identical materials, sterilization and packaging, and no new safety or effectiveness issues compared to the predicate wires, therefore, the ACS HI-TORQUE WIGGLE™ Guide Wire with MICROGLIDE® Coating may be considered safe and effective for its intended use.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 8 1999

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

Re: K984394
ACS HI-TORQUE WIGGLE™ Guide Wire with MICROGLIDE® Coating
Regulatory Class: II (two)
Product Code: 74 DQX
Dated: December 7, 1998
Received: December 8, 1998

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.

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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/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

Indications for Use Statement

510(k) Number (if known): **K984394**

Device Name: **ACS HI-TORQUE WIGGLE™ Guide Wire with MICROGLIDE® Coating**

Indications for Use:

The intended use of the ACS HI-TORQUE WIGGLE™ Guide Wire with MICROGLIDE® Coating is to facilitate the placement of the catheter by orienting the catheter tip during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA) and other interventional diagnostic or therapeutic procedures.

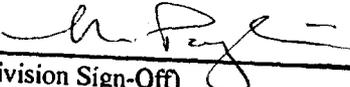
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Concurrence of CDRH, Office of Device Evaluation (ODE)

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 _____