

MAR 20 1998

K980119

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 95054
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Contact Person: Susan Silavin, Ph.D.
Date Prepared: January 12, 1998

2. Device Trade Name: ACS HI-TORQUE WHOLEY SUPRA CORE™
Guide Wire

Device Common Name: Guide Wire

Device Classification Name: Catheter Guide Wire (74DQX)

3. Predicate Devices: Wholey Hi-Torque Standard® Guide Wire (K852123, approved June 19, 1985 and K861765 approved May 30, 1986),
Hi-Torque S'Port-T™ Guide Wire (K915554, approved February 9, 1993) and
Medi-tech Amplatz Super Stiff Guide Wire (K942382, approved August 22, 1994)

4. Device Description:

The ACS HI-TORQUE WHOLEY SUPRA CORE™ Guide Wire is a steerable guide wire with a nominal diameter of 0.035 inches and three lengths: a 145, a 190 cm and a 300 cm exchange length.

5. Intended Use:

The ACS HI-TORQUE WHOLEY SUPRA CORE™ Guide Wire is intended to facilitate the placement and exchange of diagnostic and therapeutic devices during 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 ACS HI-TORQUE WHOLEY SUPRA CORE™ Guide Wire met the acceptance criteria and performed similar to the predicate Wholey Hi-Torque Standard® Guide Wire. The following tests were performed:

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

The results from the bench tests showed that the new ACS HI-TORQUE WHOLEY SUPRA CORE™ Guide Wire met acceptance criteria and performed in a manner equivalent to the predicate Wholey Hi-Torque Standard® 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, similar design and technological characteristics, equivalent performance properties, identical sterilization and packaging, and no new safety or effectiveness issues, the ACS HI-TORQUE WHOLEY SUPRA CORE™ Guide Wire may be considered substantially equivalent to the predicate Wholey Hi-Torque Standard®, Hi-Torque S'Port-T™ and the Medi-tech Amplatz Super Stiff Guide Wires.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 20 1998

Susan Silavin, Ph.D.
Senior Regulatory Affairs Coordinator
Guidant Corporation
Advanced Cardiovascular Systems, Inc.
3200 Lakeside Drive
Santa Clara, CA 95054

Re: 510(k) Number K980119
Trade Name: ASC HI-TORQUE WHOLEY SUPRA CORE™ Guide Wire
Regulatory Class: II
Product Code: DQX
Dated: January 12, 1998
Received: January 13, 1998

Dear Dr. Silavin:

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 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) 594-4618. 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

Indications for Use Statement

510(k) Number (if known): K980119

Device Name: ACS HI-TORQUE WHOLEY SUPRA CORE™ Guide Wire

Indications for Use:

The ACS HI-TORQUE WHOLEY SUPRA CORE™ Guide Wire is intended to facilitate the placement and exchange of diagnostic and therapeutic devices during intravascular procedures. It 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)

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 K980119