

SEP 11 1998

510(k) SUMMARY

This 510(k) Summary is submitted in accordance with 21 CFR Part 807, Section 807.92.

Prepared By:

Lorna Tsuda
Regulatory Affairs Coordinator

Address:

GUIDANT CORPORATION
Advanced Cardiovascular Systems, Inc.
3200 Lakeside Drive
Santa Clara, CA 95054
Telephone: 408-235-3995
Fax: 408-235-3743
Date Prepared: **June -- , 1998**

Device Trade Name:	ACS HI-TORQUE BALANCE HEAVYWEIGHT™ Guide Wire with HYDROCOAT™ Hydrophilic Coating
Device Common Name:	Guide Wire
Device Classification Name:	Catheter Guide Wire, 74DQX
Predicate Device:	ACS HI-TORQUE BALANCE MIDDLEWEIGHT™ Guide Wire

Device Description:

The ACS HI-TORQUE BALANCE HEAVYWEIGHT™ Guide Wire with HYDROCOAT™ Hydrophilic Coating is a guide wire with a nominal diameter of 0.014" and lengths of 175 cm and 190 cm extendable lengths, and a 300 cm exchange length. The proximal end of the 175 cm and 190 cm models are coined and tapered so that it has the ability to fit into the hypotube portion of the ACS DOC® Guide Wire Extension. This enables the physician to extend the working length of this guide wire to facilitate catheter exchanges.

The ACS HI-TORQUE BALANCE HEAVYWEIGHT™ Guide Wire with HYDROCOAT™ Hydrophilic Coating is constructed from a stainless steel proximal core with a nominal outer diameter of 0.014". The distal portion of the wire consists of an ELASTINITE® core. The proximal section of the wire is coated with

polytetrafluoroethylene (PTFE) and the distal, segment of the wire is coated with HYDROCOAT™ Hydrophilic Coating.

The distal tip coil has a radiopaque length of 4.5 cm. The distal end of the guide wire is available either as a straight tip that is shapeable, or as a pre-shaped "J". The 190 cm and 300 cm guide wires have markers located 90cm and 100 cm from the distal tip.

Intended Use:

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 procedures.

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 tapered distal coil.

Performance Data:

Bench testing was performed to demonstrate that the ACS HI-TORQUE BALANCE HEAVYWEIGHT™ Guide Wire with HYDROCOAT™ Hydrophilic Coating met the acceptance criteria and performed similar to the predicate HI-TORQUE BALANCE MIDDLEWEIGHT™ Guide Wire. The following tests were performed: Distal Tip Pull Test, Distal Tip Turns-to-Failure Test, Rotational Accuracy Test and Tip Flexibility Test.

The results from the bench tests showed that the new ACS HI-TORQUE BALANCE HEAVYWEIGHT™ Guide Wire with HYDROCOAT™ Hydrophilic Coating met the acceptance criteria and performed in a manner equivalent the predicate ACS HI-TORQUE BALANCE MIDDLEWEIGHT™ Guide Wire. No new safety or effectiveness issues were raised during the testing program.

Conclusions:

Since the new guide wires have the same intended use, technological characteristics, performance properties, identical sterilization and packaging, and no new safety or effectiveness issues, the ACS HI-TORQUE BALANCE HEAVYWEIGHT™ Guide Wire with HYDROCOAT™ Hydrophilic Coating may be considered substantially equivalent to the predicate ACS HI-TORQUE BALANCE MIDDLEWEIGHT™ Guide Wire.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 11 1998

Ms. Lorna Tsuda
Regulatory Affairs Coordinator
Guidant Corporation
Advanced Cardiovascular Systems, Inc.
3200 Lakeside Dr.
P.O. Box 58167
Santa Clara, CA 95054-2807

Re: K982083
Trade Name: ACS HI-TORQUE BALANCE HEAVYWEIGHT™ Guide Wire
with HYDROCOAT™ Hydrophilic Coating
Regulatory Class: II
Product Code: DQX
Dated: June 12, 1998
Received: June 15, 1998

Dear Ms. Tsuda:

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 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) 594-4586. 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" (21CFR 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, Respirator
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:

ACS HI-TORQUE BALANCE HEAVYWEIGHT™ Guide Wire with HYDROCOAT™
Hydrophilic Coating

Indications for Use:

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 procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K982083

Prescription Use ✓
(Per 21 CFR 801.109)

OR

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