

K971815

APPENDIX V
SUMMARY OF SAFETY AND EFFECTIVENESS

JUL - 9 1997

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act of 1990.

1. **Trade Name:** ACS HI-TORQUE BALANCE MIDDLEWEIGHT™
Guide Wire

Common Name: Guide Wire

2. **Device Classification:** Vascular Guide Wire

3. **Performance Standards:**

Performance standards have not been established under Section 514 of the Federal Food, Drug, and Cosmetic Act for vascular guide wires.

4. **Device Description:**

The ACS HI-TORQUE BALANCE MIDDLEWEIGHT™ Guide Wire is a steerable guide wire intended to facilitate 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. It is not intended for use in the cerebral vasculature.

The proximal and distal portions of the guide wire are constructed from a core assembly. A series of tapers and flats, which reduce the diameter of the core wire distally, yields the desired tip flexibility. The ACS HI-TORQUE BALANCE MIDDLEWEIGHT™ Guide Wire is coated with Microglide® from 40cm to 3cm back from the distal tip, while the remaining portion is coated with polytetrafluoroethylene (PTFE). Both coatings are intended to reduce friction for improved movement of the wire within the catheter.

5. **Summary of Substantial Equivalence:**

A comparison of the ACS HI-TORQUE BALANCE MIDDLEWEIGHT™ Guide Wire to the predicate ACS HI-TORQUE BALANCE® Guide Wire (K925381, approved February 12, 1993), indicates that the new guide wire is substantially equivalent to the predicate guide wire with regard to its materials, design, and functional properties, and packaging.

The ACS BALANCE MIDDLEWEIGHT™ Guide Wire is a steerable guide wire intended to facilitate 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. It is not intended for use in the cerebral vasculature. The ACS HI-TORQUE BALANCE MIDDLEWEIGHT™ Guide Wire is substantially equivalent to the ACS Hi-Torque Floppy Xtra Support® Guide Wire (K913353, approved October 23, 1991) with regard to its intended use.

The design of the new ACS BALANCE MIDDLEWEIGHT™ Guide Wire is constructed from a stainless steel core wire. Like the predicate 0.014" HI-TORQUE BALANCE® guide wire, the new guide wire design includes a series of tapers and flats which reduce the diameter of the core wire distally, yielding the desired tip flexibility. Unlike the 0.014" HI-TORQUE BALANCE® Guide Wire, the ACS HI-TORQUE BALANCE MIDDLEWEIGHT™ wire diameters and tapers along the length of the distal portion of the guide wire have been modified to yield the desired support over the distal 30 centimeters of the wire. This modification involves no new materials or processes in comparison to the predicate wire, and has no effect on the distal tip of the guide wire. Therefore, the tapers and diameters positioned at different locations proximal to the tip cannot significantly impact the safety or effectiveness of the guide wire.

6. **Testing Data:**

Bench Testing:

The tensile strengths of the guide wire distal tip and hypotube junction were determined by pull tests. These tests demonstrated that the ACS HI-TORQUE BALANCE MIDDLEWEIGHT™ Guide Wire has adequate tensile strength.

The torsional strength of the distal tip and hypotube junction were determined by turns-to-failure tests. This test showed that the ACS HI-TORQUE BALANCE MIDDLEWEIGHT™ Guide Wire has adequate torsional tip strength.

The correlation between rotation of the proximal end and the corresponding rotation of the distal end of the guide wire was determined by the rotational accuracy test. This test showed that the ACS HI-TORQUE BALANCE MIDDLEWEIGHT™ Guide Wire has an adequate torque response.

The tip flexibility testing demonstrated that tip flexibility of the ACS HI-TORQUE BALANCE MIDDLEWEIGHT™ Guide Wire has acceptable tip flexibility.

In vivo Testing:

An animal study was completed to evaluate and compare the performance of the ACS HI-TORQUE BALANCE MIDDLEWEIGHT™ Guide Wire to that of the ACS Hi-Torque Floppy Xtra Support® Guide Wire (K913353, October 23, 1991) when used in combination with the Johnson and Johnson (JJIS) Stent Delivery System, the DVI AtheroCath-GTO Atherectomy Catheter, and with the CVIS UltraCrossIntravascular ultrasound catheter.

The results of these studies show that the ACS HI-TORQUE BALANCE MIDDLEWEIGHT™ Guide Wire performs as well as or better than the ACS Hi-Torque Floppy Xtra Support® Guide Wire in the majority of the performance parameters when used to facilitate the placement of equipment, such as atherectomy and compatible stent devices, and during other diagnostic and therapeutic intravascular procedures.

Biocompatibility:

Since the materials for the ACS HI-TORQUE BALANCE MIDDLEWEIGHT™ Guide Wire are identical to those of the predicate 0.014" HI-TORQUE BALANCE® Guide Wire, the biocompatibility data from the predicate device were used to demonstrate that the materials and processes utilized in the new guide wire are biocompatible for short term use within the vascular system.

7. **Sterilization:**

The ACS BALANCE MIDDLEWEIGHT™ Guide Wire is sterilized by the same methods and following the same parameters as those used for the predicate 0.014" HI-TORQUE Balance® Guide Wire (K925381, approved February 12, 1993).

8. **Conclusion:**

The ACS HI-TORQUE BALANCE MIDDLEWEIGHT™ Guide Wire is substantially equivalent to the predicate devices, the 0.014” HI-TORQUE BALANCE® Guide Wire (K925381, approved February 12, 1993), and the Hi-Torque Floppy Xtra Support® Guide Wire (K913353, approved October 23, 1991).

Signed:



Mona Mirapuri
Regulatory Affairs Coordinator



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JUL - 9 1997

Re: K971815
ACS HI-TORQUE BALANCE MIDDLEWEIGHT™ Guide Wire
Regulatory Class: II (two)
Product Code: DQX
Dated: May 16, 1997
Received: May 17, 1997

Dear Ms. Mirapuri:

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 requirement, 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): _____

Device Name: ACS HI-TORQUE BALANCE MIDDLEWEIGHT™ Guide Wire

Indications for Use:

The ACS HI-TORQUE BALANCE MIDDLEWEIGHT™ Guide Wire is a steerable wire intended 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.

(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)

Tam A. R.
(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K971815