

Summary of Safety and Effectiveness**General Provisions**

Trade Name: ATW Marker Wire Steerable Guidewire

Common/Classification Name: Catheter Guide Wire

Name of Predicate Devices

Wizdom Marker Wire Steerable Guidewire
Stabilizer Marker Wire Steerable Guidewire
ST Steerable Guidewire

Classification

Class II

Performance Standards

The FDA under section 514 of the Food, Drug and Cosmetic Act has not established performance standards.

Intended Use and Device Description

The Cordis ATW Marker Wire Steerable Guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature. In addition, the Cordis ATW Marker Wire Steerable Guidewires are intended to facilitate the alignment of interventional devices and function as a measurement tool.

The device description of the ATW Marker Wire Steerable Guidewire is as follows.

- Stainless Steel Corewire,
 - Radiopaque platinum / nickel coilwire,
 - Radiopaque Marker Bands with optional spacing (See package labeling), and
 - PTFE coating on shaft.
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Biocompatibility

All materials used in the ATW Marker Wire Steerable Guidewires are biocompatible.

Summary of Substantial Equivalence

The ATW Marker Wire Steerable Guidewires are substantially equivalent to the previously cleared ST Steerable Guidewire, Wizdom Marker Wire, and Stabilizer Marker Wire Steerable Guidewires.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JAN 13 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Dennis Griffin
Manager, Regulatory Affairs
Cordis Corporation
P.O. Box 025700
Miami, FL 33102-5700

Re: K994358
Trade Name: ATW Marker Wire Steerable Guidewire
Regulatory Class: II
Product Code: DQX
Dated: December 20, 1999
Received: December 27, 1999

Dear Mr. Griffin:

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

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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,



Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular,
Respiratory and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 2

Indications for Use Statement

510(k) Number
(if known)

The 510(k) number has not yet been assigned.

Device Name

ATW Marker Wire Steerable Guidewire

Indications for
Use

The Cordis guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature. In addition, the Cordis ATW Marker Wire Steerable Guidewires are intended to facilitate the alignment of interventional devices and function as a measurement tool.

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 Use

Christy M. Allen for Witten
(Division Sign-Off)

Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K994358