

JAN - 5 1998

## Summary Of Safety And Effectiveness

**General Provisions**

The name of the device is:

Proprietary Name	Common or Usual Name
Cordis Hydronol Steerable Guidewire	Catheter Guide Wire

**Predicate Device**

The name of the predicate devices are:

- Terumo Radifocus Glidewire
- LRM Steerable Hydrophilic Guidewire

**Classification**

The FDA has classified catheter guide wires as:

- Class II, 21CFR 870.1330, 74 DQX

**Performance Standards**

Performance standards have not been established by the FDA under Section 514 of the Food, Drug, and Cosmetic Act.

**Indications for Use**

The Cordis Hydronol Steerable Guidewires are designed for use in angiographic procedures to introduce and position catheters and interventional devices within the peripheral vasculature.

**Device Description**

The Cordis Hydronol Steerable Guidewire is constructed from a superelastic nitinol core wire. A hydrophilic coating is applied over the guidewire. Cordis Hydronol Steerable Guidewires have a flexible, shapeable, and highly radiopaque platinum alloy coil on the distal tip.

*Continued on next page*

## Summary Of Safety And Effectiveness, Continued

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**Biocompatibility** All appropriate Biocompatibility tests were successfully performed on the materials used for the Cordis Hydronol Steerable Guidewires per ISO 10993-1.

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**Summary of Substantial Equivalence** The Cordis Hydronol Steerable Guidewire is similar in design, construction, indication for use and performance characteristics to other commercially available hydrophilic steerable guidewires.

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<sup>1</sup> Any statement of substantial equivalence to another product is required by 21 CFR 807.87, and relates only to whether the present product can be marketed without prior reclassification or clinical approval. The present submission is therefore not related to the coverage of any patent, and is not to be interpreted as an admission or used as evidence in a patent infringement lawsuit. As the Commissioner of the FDA has stated, "...a determination of substantial equivalence under the federal Food, Drug, and Cosmetic Act relates to the fact that the product can lawfully be marketed without pre-market approval or reclassification. This determination is not intended to have any bearing whatever on the resolution of patent infringement suits." 42 Fed. Reg. 42,520, et seq. (1977).



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Jacqueline Zimovan  
Regulatory Affairs Associate  
Cordis Corporation  
P.O. Box 025700  
Miami, Florida 33102-5700

JAN - 5 1998

Re: K973845  
Cordis Hydronol Steerable Guidewire  
Regulatory Class: II (two)  
Product Code: DQX  
Dated: October 7, 1997  
Received: October 8, 1997

Dear Ms. Zimovan:

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 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) 594-4648. 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,

A handwritten signature in black ink that reads "Thomas J. Callahan". The signature is written in a cursive style with a large, prominent initial 'T'.

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

510(K) Number (if known): [To be assigned by the FDA]

Device Name: Hydronol Steerable Guidewire

Indications for Use: The Cordis Hydronol Steerable Guidewires are designed for use in angiographic procedures to introduce and position catheters and interventional devices within the peripheral vasculature.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

*Tara A Ryp*

(Division Sign-Off)  
Division of Cardiovascular Respiratory,  
and Neurological

510(k) Number     K973845    

Prescription Use   ✓    
(Per 21 CFR 801.109)

OR

Over-The Counter Use \_\_\_\_\_