

0-000016
K972518

Summary of Safety and Effectiveness

NOV - 4 1997

General Provisions

Common or Usual Name: Continuous Flush Catheter

Trade Name: CES Infusion Catheters, including

- Transit™ Infusion Catheter
- RapidTransit™ Infusion Catheter
- Speedster™ Infusion Catheter
- Prowler™ Infusion Catheter

Predicate Devices

The predicates are listed in the table below:

Device	Company	510(k) Number/ Clearance Date	Product Code	Predicate for:
CES Infusion Catheters	Cordis Endovascular Systems, Inc.	K965181, 3/21/97	KRA	Design, materials, sterilization and packaging
Venture™ II Infusion Catheter	Scimed Life Systems	K945904, 5/19/95	KRA	Indications/claims
UltraFuse-X™ Infusion/Guide Wire Exchange Catheter	Scimed Life Systems	K952872, 7/27/95	KRA	Indications/claims

Classification

Class II

Performance Standards

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

Intended Use	CES Infusion Catheters are intended to be used as a mechanism for the selective infusion of various diagnostic, embolic and therapeutic agents into the peripheral, coronary and neurovasculatures. The catheters can also be used to exchange one guidewire for another or provide support to facilitate the placement of guidewires.
Device Description	The CES Infusion Catheters contain a single lumen and a variable stiffness shaft in order to traverse and deliver agents to the coronary, peripheral and neurovasculatures. The outside of the shaft includes a hydrophilic coating and the lumen is lined with PTFE in order to increase lubricity and trackability. The proximal shaft is reinforced with a stainless steel braid to enhance pushability.
Biocompatibility	All applicable biocompatibility tests were successfully performed on the CES Infusion Catheters.
Summary of Substantial Equivalence	The CES Infusion Catheters are substantially equivalent* in design, materials, sterilization and indications for use to other commercially available catheters.

* A statement of substantial equivalence to another product is required by 21CFR 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

NOV - 4 1997

Ms. Lisa Wells
Cordis Endovascular Systems, Inc.
14740 N.W. 60th Avenue
Miami Lakes, Florida 33014

Re: K972518
CES Infusion Catheters
Regulatory Class: II (two)
Product Code: 74 KRA
Dated: October 22, 1997
Received: October 23, 1997

Dear Ms. Wells:

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 (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 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) 594-4639. 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

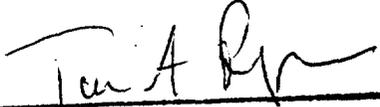
510(k) Number: K972518

INDICATIONS FOR USE

CES Infusion Catheters are intended to be used as a mechanism for the selective infusion of various diagnostic, embolic and therapeutic agents into the peripheral, coronary and neurovasculatures. The catheters can also be used to exchange one guidewire for another or to provide support to facilitate the placement of guidewires.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)



(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K972518