

Appendix A - Summary of Safety and Effectiveness

0-000029

K974222

FEB 10 1998

K974222
0-000030

510(k) Summary of Safety and Effectiveness

General Provisions

Common name:
• CES MassTRANSIT Infusion Catheter

Predicate Devices

The predicate devices are listed in the table below.

| Device | Company | 510 (k) Number, Concurrency Date | Product Code |
|-----------------|-----------------------------------|--|--------------|
| CES TRANSIT | Cordis Endovascular Systems, Inc. | K952874, K936260 K936282, K965181, K972518 | DQO KRA |
| FasTRACKER® 325 | Target Therapeutics | K960806* | DQO* |
| JETSTREAM® 327 | Medtronic | K953900, K953892* | DQO KRA |

* This information is assumed based on our best current knowledge.

Classification

Class II

Performance Standard

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

Intended use

The MassTRANSIT is indicated for the infusion of various diagnostic, therapeutic and embolic agents in the peripheral, coronary, and neurovasculature.

Device Description

The MassTRANSIT is a single lumen catheter designed to access small, tortuous vasculature for the delivery of diagnostic, embolic and therapeutic agents. The shaft tapers from 3.0F proximal to 2.8F distally. The catheter has a hydrophilic coating to provide lubrication for navigation of vessels. The inner lumen is lined with PTFE to facilitate movement of guidewires and other devices.

510(k) Summary of Safety and Effectiveness (cont.) ⁰⁻⁰⁰⁰⁰³¹

Biocompatibility All appropriate biocompatibility tests have been performed according to the FDA modified matrix of ISO-10993 (Blue Book Memorandum G95-1). The catheters demonstrated compatibility with biological tissue by meeting the acceptance criteria stipulated in the test protocols.

Summary of Substantial Equivalence The CES MassTRANSIT Infusion Catheter is similar in its basic design, construction, indication for use and performance characteristics to the predicate devices.²

² 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

FEB 10 1998

Ms. Ariel MacTavish
Sr. Regulatory Affairs Associate
Cordis Corporation
P.O. Box 025700
Miami, FL 33102-5700

Re: K974222
CES Mass Transit™ Infusion Catheter
Regulatory Class: II (two)
Product Code: 74 KRA
Dated: November 7, 1997
Received: November 12, 1997

Dear Ms. MacTavish:

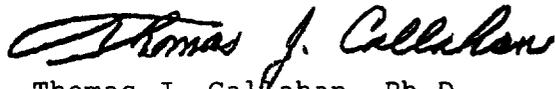
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

0-000035

510 (k) Number: K974222

Indications for Use Statement

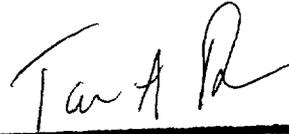
CES MassTRANSIT Infusion Catheters are indicated for the selective infusion of various diagnostic, therapeutic and embolic agents into the peripheral, coronary and neurovasculatures.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use



(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K974222