SEP 17 1998

K983003

Attachment 4

Summary of Safety and Effectiveness

General Provisions	Trade Name: MASS TRANSIT Infusion Catheter Common/Classification Name: Continuous Flush Catheter
Name of Predicate Devices	Cordis Endovascular Systems, Inc. MASS TRANSIT Infusion Catheter
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 MASS TRANSIT Infusion Catheters are indicated for the selective infusion of various diagnostic, therapeutic, and embolic agents into the peripheral, coronary, and neurovasculature. The device description for the MASS TRANSIT Infusion Catheters is as follows. • Single lumen catheter designed to access small, tortuous vasculature for the delivery of diagnostic, embolic, and therapeutic agents. • The shaft tapers from 3.0F proximally 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.
Biocompatibility	All materials used in the MASS TRANSIT Infusion Catheters are biocompatible.
Summary of Substantial Equivalence	The MASS TRANSIT Infusion Catheters are substantially equivalent to the previously cleared MASS TRANSIT Infusion Catheters.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 17 1998

Mr. Martine D. Schneider
Sr. Regulatory Affairs Associate
Cordis Endovascular System, Inc.
14000 N.W. 57th Ct.
Miami Lakes, FL 33014

Re: K983003
Trade Name: Mass Transit Infusion Catheter
Regulatory Class: II
Product Code: KRA
Dated: August 27, 1998
Received: August 28, 1998

Dear Mr. Schneider:

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.

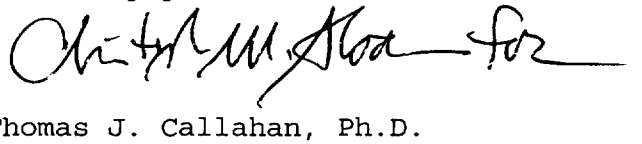
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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) 594-4586. 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,



Thomas J. Callahan, Ph.D.
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	MASS TRANSIT Infusion Catheter Catheters
Indications for Use	The MASS TRANSIT Infusion Catheters are indicated for the selective infusion of various diagnostic, therapeutic, and embolic agents into the peripheral, coronary, and neurovasculature.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for TJC

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K983003

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