OCT 2 8 1999

K993266

Attachment 4

Summary of Safety and Effectiveness

General Provisions	Trade Name: Prowler Plus Infusion Catheter Common/Classification Name: Infusion Catheter
Name of Predicate Devices	Cordis Endovascular Systems, Inc. Prowler Infusion Catheter, and Rapid 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 Prowler Plus Infusion Catheters are intended to be used as a mechanism for the infusion of various diagnostic, embolic, and therapeutic agents into the vascular systems (Neuro, Peripheral, Coronary), for Guidewire Exchange/Support, and for superselective angiography of the peripheral and coronary vasculatures. The Prowler Plus is a single lumen catheter featuring a stiff proximal shaft and a flexible distal section. The catheter's inner diameter accommodates guidewires of .018" and smaller. The catheter body is radiopaque with a distinguishable marker at the distal tip. It includes a hydrophilic coating on the outside of the shaft as well as a PTFE liner on the inner lumen.
Summary of Studies	Design verification testing showed that the Prowler Plus Infusion Catheter performs as well or better than the predicate devices tested. No new questions of safety and effectiveness were raised. Design verification testing included: • Pull Strength Test • Trackability Test • Dimensional Testing (Tip OD, ID, Body OD, Joint OD, Length Assembly, Hub Taper) • Static Burst Pressure Test • Alternative Flow Rate Calculation • Air Aspiration • Linear Stiffness Test (Boink) • Shapeability Test
Biocompatibility	All materials used in the Prowler Plus Infusion Catheters are biocompatible.
Summary of Substantial Equivalence	The Prowler Plus Infusion Catheters are substantially equivalent to the previously cleared Prowler and Rapid Transit Infusion Catheters.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 28 1999

Ms. Maritza Celaya
Sr. Regulatory Affairs Specialist
Cordis Endovascular SystemS, Inc.
p.o. Box 025700 Ct.
Miami Lakes, FL 33102-5700

Re: K993266
Trade Name: Prowler Plus Infusion Catheter
Regulatory Class: II
Product Code: KRA
Dated: September 29, 1999
Received: September 30, 1999

Dear Ms. Celaya:

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,

for 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	Prowler Plus Infusion Catheters.
Indications for Use	The Prowler Plus Infusion Catheters are intended to be used as a mechanism for the infusion of various diagnostic, embolic, and therapeutic agents into the vascular systems (Neuro, Peripheral, Coronary), for Guidewire Exchange/Support, and for superselective angiography of the peripheral and coronary vasculatures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Written.

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K993266

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____