DEC 23 1998

K984500

Attachment 4

Summary of Safety and Effectiveness

General Provisions	Trade Name: Cordis Brite Tip Catheter Sheath Introducer Common/Classification Name: Catheter Introducer System
Name of Predicate Devices	Cordis Brite Tip Catheter Sheath Introducer
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 and Device Description	Cordis Catheter Sheath Introducers are intended for use in arterial and venous procedures requiring percutaneous introduction of intravascular devices. The device description of the Brite Tip CSI is as follows. The system consists of an introducer, a mini-guidewire, and a vessel dilator. The introducer consists of a cannula of co-extruded polyethylene with barium sulfate, a high density polyethylene body, and polyurethane sideport extension. The radiopaque tip is made of a blend of tungsten, polyethylene, and zinc stearate. • 4 - 11 French • 3 - 120 cm length • .035" - 038' mini guidewire
Biocompatibility	All materials used in the Brite Tip CSI's are biocompatible.
Summary of Substantial Equivalence	The Brite Tip CSI's are substantially equivalent to the previously cleared Brite Tip CSI's.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 23 1998

Ms. Ariel MacTavish
Sr. Regulatory Affairs Associates
Cordis Corporation
14420 N.W. 60th Avenue
Miami Lakes, FL 33014

Re: K984500
Trade Name: Cordis Brite Tip Catheter Sheath Introducer System
Regulatory Class: II
Product Code: DYB
Dated: December 14, 1998
Received: December 17, 1998

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 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

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)

Device Name Brite Tip Catheter Sheath Introducer

Indications for Use Cordis Catheter Sheath Introducers are intended for use in arterial and venous procedures requiring percutaneous introduction of intravascular devices.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K984500

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