00-00026 K974448

PREMARKET NOTIFICATION 510(k)
Cordis, a Johnson and Johnson company
Brite Tip® Catheter Sheath Introducer
(Modification K971608)

FEB 6 1998

SUMMARY OF SAFETY AND EFFECTIVENESS

I. General Provisions

Common or Usual Name: Catheter Sheath Introducer or Sheath Introducer System.
Proprietary Name: Cordis Brite Tip® Catheter Sheath Introducer System.

II. Name of Predicate Device

Brite Tip® Catheter Sheath Introducer System, K971608.

III. Classification

Class II

IV. Performance Standards

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

V. Intended Use and Device Description

The line extensions for Brite Tip® Catheter Sheath Introducer System is indicated for use in arterial and venous procedures requiring percutaneous introduction of catheters and other intravascular devices.

As with other currently marketed Cordis CSIs mentioned in this submission, these devices provide vascular access for various intravascular devices through the valve while simultaneously maintaining hemostasis. Infusion of fluids into the vasculature and withdrawal of blood from the vasculature are possible using the sheath sideport.

VI. Biocompatibility

All materials used in the line extensions for Cordis Brite Tip® Catheter Sheath Introducer System had been successfully tested on previously concurred devices. Since all appropriate biocompatibility tests were previously performed on these materials, testing was not repeated.

VII. Summary of Substantial Equivalence

The modified Cordis Brite Tip® Catheter Sheath Introducer System is similar in design, constructions, indication for use, and performance characteristics to other commercially available sheath introducers.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Rockville MD 20857

FEB 6 1998

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

Re: K974448
Brite Tip® Catheter Sheath Introducer System
Regulatory Class: II (two)
Product Code: 74 DYB
Dated: November 24, 1997
Received: November 25, 1997

Dear Ms. MacTavish:

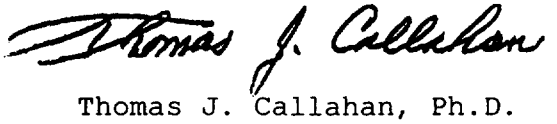
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

00-00051

PREMARKET NOTIFICATION 510(k)
Cordis Corporation
Brite Tip® Catheter Sheath Introducer

510(k) Number (if known): K974448

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 IS NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(D Off)
Cardiovascular, Respiratory,
gical Devices
510(k) Number K974448

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