

K971608

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

JUL 21 1997

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 Devices

Brite Tip® Catheter Sheath Introducer, K 954595, October 02, 1995

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

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 appropriate biocompatibility tests were performed on the materials used in the modified Brite Tip® Catheter Sheath Introducer.

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VII. Summary of Substantial Equivalence

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

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).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

Elena S. Jugo, M.D.
Cordis Corporation
P.O. Box 025700
Miami, Florida 33102-5700

JUL 21 1997

Re: K971608
Brite Tip® Catheter Sheath Introducer
Regulatory Class: II (two)
Product Code: DYB
Dated: April 30, 1997
Received: May 1, 1997

Dear Dr. Jugo:

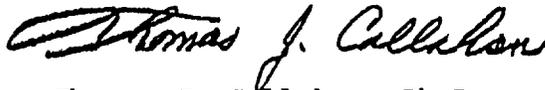
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

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

510(k) Number (if known): K971608

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)



(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K971608

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use