MAR 2 6 2004

510(k) Summary

510(k) Number: K034025

Date Prepared
December 23, 2003

Submitter's Name, Address, Telephone Number
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Contact Person
Anne M. Kulis
Vice President, Regulatory Affairs

Device Name

Proprietary Name:	NMT Medical Transseptal Sheath Set
Common Name:	Introducer, Introducer Sheath, Sheath
Classification Name:	Catheter Introducer

Device Classification
Class II, §870.1340

Predicate Device
COOK Check-Flo® Transseptal Introducer Sets
COOK Incorporated

K134025

Device Description

The NMT Medical Transseptal Sheath Set consists of a long and short introducer sheath set. The long sheath set is comprised of a curved 75cm length introducer sheath and curved 81 cm length dilator. The short sheath set is comprised of a straight 12cm length introducer sheath and straight 19cm length dilator.

Intended Use

The NMT Transseptal Sheath Set is indicated for percutaneous introduction of various cardiovascular devices into the left side of the heart through the atrial septum.

Summary of Technological Characteristics of Current Device Compared to the Predicate Device

The technical characteristics of the applicant device are substantially equivalent to the predicate device with respect to indications for use, product design, materials, packaging, labeling and sterilization methods.

Support of Substantial Equivalence

In-vitro and biocompatibility tests were conducted to compare the NMT Transseptal Sheath Set to the predicate device. Test results demonstrate that the applicant device met performance specification requirements and is substantially equivalent to the predicate device. Additionally, the NMT Medical Transseptal Sheath Set met the applicable requirements of ISO-10993-1, ISO-11070, ISO-10555 and ISO 594-2. Additionally, indications for use of the applicant device and the predicate device are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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NMT Medical, Inc.
c/o Ms. Anne M. Kulis
Vice President, Regulatory Affairs
27 Wormwood Street
Boston, MA 02210

Re: K034025
NMT Medical Transseptal Sheath Set
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter introducer
Regulatory Class: Class II
Product Code: DYB
Dated: December 23, 2003
Received: December 29, 2003

Dear Ms. Kulis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer 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,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K034025**

Device Name: **NMT Medical Transseptal Sheath Set**

Indications For Use:

The NMT Medical Transseptal Sheath Set is indicated for percutaneous introduction of various cardiovascular devices into the left side of the heart through the atrial septum.

Prescription Use _X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Kochner

(Division Sign-Off)
Division of Cardiovascular Devices

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