MAY 18 2006

K061119

510(k) Summary

Submitter

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Contact Person

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Date Prepared

April 20, 2006

Trade Name

Enpath Medical Steerable Sheath

Common Name

Catheter Introducer

Classification Name

Percutaneous Catheter (21 CFR 870.1250, Product Code DQY)

Predicate Device

Enpath Medical Steerable Sheath; K043489.

Device Description

The Enpath Steerable Sheath is a guide catheter (delivery sheath) which has a distal tip that deflects to create a variable curve shape. The deflection is controlled through a handle mechanism with the ability to lock at any point along the catheter tip curve travel. The handle incorporates a luer fitting or a hemostasis valve.

The Enpath Steerable Sheath will be used clinically in the same way that a guide catheter or sheath is used as part of an interventional procedure, to gain access to locations that are not easily accessed with existing tools. Certain parts of the vasculature are difficult to access because of occlusion, tortuosity, or simply because standard catheters do not provide the necessary curve angle(s). The Steerable Sheath, with its deflection capability, enables access to these areas. Primary applications for the product remain focused on access for Pulmonary Vein Ablation, Transseptal access, Renal Stenting, and Carotid Stenting.

Intended Use

The Enpath Medical Steerable Sheath is intended to be used to facilitate the placement of interventional devices into the peripheral and coronary systems.

Comparison of Technological Characteristics

All technological characteristics of the Enpath Steerable Sheath are substantially equivalent to the predicate device (K043489) including biocompatibility, product design, function, packaging, sterilization and labeling. The molded handle configuration incorporates a handle material change and an integrated deflection and locking mechanism. The molded handle configuration does not alter the intended use or fundamental scientific technology of the device.

Summary of Studies

The performance testing for this device included testing to verify that the device functions in a safe and effective manner. The performance testing included the device specifications, functional testing of the articulation, deflection radius, deflection force, hemostatsis of the valve portion, deflection cycle testing and other testing as applicable to this device. Test results verify that the device performs per specification requirements and is equivalent to the predicate device without creating additional risk to the patient or user.
No clinical evaluations for this submission have been conducted.

Substantial Equivalence

The molded handle Steerable Sheath is as safe, as effective, and performs as well as, and is substantially equivalent to the original "cleared" machined handle Enpath Steerable Sheath, K043489. The design modification of the sheath handle assembly does not affect the indications for use nor alter the fundamental scientific technology of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 18 2006

Enpath Medical Inc.
c/o Mr. James Jenkins
Regulatory Associate
15301 Highway 55 West
Minneapolis, MN 55447

Re: K061119
Enpath Medical Steerable Sheath
Regulation Number: 21 CFR 870.1250
Regulation Name: Catheter Introducer
Regulatory Class: II
Product Code: DQY
Dated: April 20, 2006
Received: April 21, 2006

Dear Mr. Jenkins:

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 (240) 276-0120. 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/industry/support/index.html.

Sincerely yours,

Donna R. Lochner

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

Enclosure

VI Indications for Use

510(k) Number (if known): ~~Not Assigned~~ K061119

Device Name: Enpath Medical Steerable Sheath

Indications for Use: The Enpath Medical Steerable Sheath is intended to be used to facilitate the placement of interventional devices into the peripheral and coronary systems.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vachon

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K061119