K043489

IV. 510(k) Summary

MAY 1 9 2005

Submitter
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Date Prepared
December 12, 2004

Trade Name
Enpath Deflectable Catheter

Submission Correspondent
Karyl Haskell
Regulatory Affairs Manager

Submission Correspondent Telephone, Fax, and Email
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Common Name
Catheter Introducer

Intended Use
The Enpath Deflectable Catheter is intended to be used to facilitate the placement of interventional devices into the peripheral and coronary systems.

Predicate Device
- Medtronic, Inc: Medtronic Model 10600 Deflectable Catheter System 510(k) K013517

Device Description

The Enpath Deflectable Catheter 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 product specifications, drawings and photographs are located in Appendix E of this submission.

The Enpath Deflectable Catheter 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 Deflectable Catheter, with its deflection capability, enables access to these areas. Primary applications for product focus on access for Pulmonary Vein Ablation, Transseptal access, Renal Stenting, and Carotid Stenting.

The deflectable catheter shaft is constructed of Pebax, lined with PTFE and filled with Barium Sulfate as a radiopacifier. The catheter hub is overmolded Nylon 12 (10% glass filled). The catheter hub houses a hemostasis valve which is molded silicone rubber.

The deflectable catheter handle is made of machined ABS, and is cyanoacrylate bonded onto the deflectable shaft. The handle configuration may vary based on specific user requirements. The handle modifications will not effect the functionality or safety of the device. For example, the shape of the handle, method of deflection (i.e. slide, rotate etc) may change, but the curve of the deflection and the shaft of the device will remain the same. Any handle changes will be validated and appropriately tested to ensure safety and effectiveness.

The dilator tube is made of MDPE (high density/low density polyethylene blend) and has a hub made of HDPE resin overmolded onto the dilator tube. The dilator assembly is coated with silicone lubricant to reduce insertion force through the sheath hemostasis valve.

The deflectable tip sheath size range is from 7 FR (ID) to 14 FR. The materials and construction are the same for all French sizes.

The Deflectable Tip Sheath will be packaged and EtO sterilized for single use in a Tyvek pouch. The sterile kit packaging configuration will include the deflectable catheter and the dilator. The product may be provided as a bulk non-sterile device to OEM customers for further processing and packaging.

Technological Characteristics / substantially equivalent devices

The Enpath Deflectable Catheter is technologically equivalent to the predicate device:

Enpath Deflectable Catheter	Predicate Device	Predicate Device Manufacturer	510(k)
Deflectable Catheter	Medtronic Model 10600 Deflectable Catheter System	Medtronic, Inc Minneapolis MN 55432	K013517
Deflectable Catheter Dilator Adjustable Hemostasis Valve	Medtronic Model 10600 Catheter System	Medtronic, Inc Minneapolis MN 55432	K013517

In addition, the sterilization process and biocompatibility of the Enpath Deflectable Catheter are substantially equivalent to the above documented predicate device, the Medtronic Model 10600 510(k) K013517

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, hemostasis of the valve portion, deflection cycle testing and testing consistent with the requirements in FDA 'Guidance on premarket notification [510(k)] submission for short-term and long-term intravascular catheters (3/19/1995)' as applicable to this device. Test results verify that the device performs per specification requirements.

Statement of Substantial Equivalence

Through the data and information presented, Enpath concludes that the Enpath Deflectable Catheter is substantially equivalent to the predicate device:

Medtronic Model 10600 Deflectable Catheter System 510(k)
K013517

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 19 2005

Enpath Medical Incorporated
c/o Ms. Karyl Haskell
Regulatory Affairs Manager
Enpath Medical Incorporated
15301 Highway 55 West
Minneapolis, MN 55447

Re: K043489
Trade/Device Name: Enpath Deflectable Catheter
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: April 15, 2005
Received: April 18, 2005

Dear Ms. Haskell:

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,

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

Enclosure

V. Indications for Use

Indications for Use

510(k) Number (if known): Not Assigned K043489

Device Name: Enpath Deflectable Catheter

Indications For Use: The Enpath Deflectable Catheter is intended to be used to facilitate the placement of interventional devices into the peripheral and coronary systems.

Prescription Use ✓ 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)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K043489