K033540

MAY 25 2004

510(k) Summary

1. Sponsor's Information

Sponsor's Name and Address:
Medtronic Vascular
3576 Unocal Place
Santa Rosa, CA 95403

Sponsor's Phone/ Fax Number:
(707) 525-0111
(707) 591-7406

Contact Person:
Leisa Martinez
Regulatory Affairs Associate
Phone: (707) 541-3259
Fax: (707) 591-7406
E-mail: leisa.martinez@medtronic.com

Submitted:
April 30, 2004

2. Device Information

Name:
TransXchange Support Catheter

Trade Name:
N/A

Classification:
Common Name: Intravascular Catheter
Classification Name: Percutaneous Catheter (21 CFR 870-1250)

3. Predicate Device Information:

Name:	Spectranetics Support Catheter
Manufacturer:	Spectranetics
510(k) Number:	K991059
Clearance Date:	October 19, 1999

4. Device Description

The TransXchange Support Catheter is designed to perform the following functions during percutaneous intravascular procedures:

1. Support a 0.014" guidewire during introduction of catheters with lumens of 0.035" or greater over a 0.014" guidewire. The TransXchange Support Catheter is designed to assist in the introduction of catheters with lumens of 0.035" or greater over a 0.014" guidewire. The TransXchange Support Catheter acts to fill the annular space between the smaller guidewire and larger catheter lumen.
2. Allow for the exchange of guidewires through its lumen
3. Infusion of fluids such as saline or diagnostic contrast agents through its lumen into the vascular system using pressures up to 150 psi

The TransXchange Support Catheter in constructed of 5 components: a single lumen high density polyethylene tubing with a tapered distal tip, a proximal female luer hub, a two piece strain relief constructed of polyolefin, a distal platinum iridium marker band, and Loctite 4304 Cyanoacrylate Adhesive.

5. Intended Use of Device

The TransXchange Support Catheter is a guidewire exchange and infusion device designed for use in the peripheral vascular system. The catheter is intended to support a guidewire during access of vessels, allow for exchange of guidewires, and provide a conduit for the delivery of saline solutions or diagnostic contrast agents.

6. Technological Characteristics:

A. Comparison of Technological Characteristics

The TransXchange Support Catheter is substantially equivalent to the currently cleared Spectranetics Support Catheter (K0991059). The subject and predicate stents are identical technology and are intended to support a guidewire during access of the vasculature, to allow for the exchange of guidewires, and to infuse saline or diagnostic contrast agent. The subject device offers a smaller catheter diameter. The subject and predicate stents are both intended to meet clinical needs. The difference between the subject and predicate devices are minor and are not relevant to the ability of the subject device to perform as intended.

B. Nonclinical testing

Preclinical testing was conducted to confirm the safe and effective performance of this device as well as the biocompatibility of the device.

C. Sterilization

The TransXchange Support Catheter is provided sterile. The device is not intended for reuse or resterilization.

D. Conclusion

The TransXchange Support Catheter is substantially equivalent to the currently cleared Spectranetics Support Catheter (K991059) and meets clinical needs of the physicians.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 25 2004

Medtronic Vascular
c/o Ms. Leisa Martinez
3576 Unocal Pl.
Santa Rosa, CA 95403

Re: K033540
Trade/Device Name: TransXchange Support Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (two)
Product Code: DQY
Dated: August 8, 2003
Received: November 10, 2003

Dear Ms. Martinez:

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,

Donna R. Bachner

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): K033540

Device Name: TransXchange Support Catheter

Indications For Use:

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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. Vochmes

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K033540