K033678

FEB 2 3 2004

Premarket Notification 510(k) Summary

Submitted By:
Michael J. Ryan
RA Manager
Spectranetics Corporation
96 Talamine Court
Colorado Springs, CO 80907
Signature and Date: Michael J. Ryan 21 Nov 03

Device Trade Name: Spectranetics Quick-Cross Support Catheter.
Common Name: Intravascular Catheter
Classification Name: Percutaneous Catheter, CFR 870.1250

Device Description: The Spectranetics Quick-Cross Support Catheters are intravascular catheters, available in seven (7) models:

518-032	0.014" diameter catheter,	135cm length
518-033	0.018" diameter catheter	90 cm length
518-034	0.018" diameter catheter	135 cm length
518-035	0.018" diameter catheter	150 cm length
518-036	0.035" diameter catheter	90 cm length
518-037	0.035" diameter catheter	135 cm length
518-038	0.035" diameter catheter	150 cm length

Model number 518-032 has a shaft of varying stiffness with a proximal shaft diameter of 3.0 Fr. tapering to a distal shaft diameter of 1.9 Fr.

Model numbers 518-033, 518-034, and 518-035 have a shaft of varying stiffness with a proximal shaft diameter of 3.4 Fr. tapering to a distal shaft diameter of 2.2 Fr.

Model numbers 518-036, 518-037, and 518-038 have a shaft of varying stiffness with a proximal shaft diameter of 4.8 Fr. tapering to a distal shaft diameter of 3.7 Fr.

	All models have three (3) radiopaque markers located at their tapered distal tip. A standard female luer is placed on the proximal end of each model. The distal 40 cm of each model is coated with a lubricious, hydrophilic coating. Predicate devices of this type with similar intended uses have been classified into Class II.
Indications for Use:	The Spectranetics Quick-Cross Support Catheters are designed for use in the vascular system. The catheters are intended to support a guidewire during access of the vasculature, allow for exchange of guidewires, and provide a conduit for the delivery of saline solutions or diagnostic contrast agents.
Substantial Equivalence:	This product is substantially equivalent in design, composition, function, and intended use to the Spectranetics Support Catheters, 510(k) K991059 and K022138.
Technological Characteristics & Nonclinical Testing Summary:	The Spectranetics Quick-Cross Support Catheters are similar in design, construction, indications, target population, risk analysis, performance and materials to the predicate devices, the Spectranetics 0.014" and 0.018" Support Catheters, K991059, and the Spectranetics 0.035" Support Catheter, K022138. Spectranetics New Production Introduction procedure has been used in concert with the Quality System Regulations for the introduction of the Quick Cross Support Catheter. The design validation protocols and risk analysis addressed all known aspects of the device including tensile strength, functionality, visibility, flow rate, sterility, and biocompatibility. Testing performed for the Spectranetics Support Catheter provides reasonable assurance that the device will perform in a safe and effective manner when used as indicated
	The Spectranetics Quick-Cross Support Catheters are similar in the indications for use as the Spectranetics Support Catheters K991059 and K022138.
Conclusions:	The results of the bench testing demonstrate that the Spectranetics Quick-Cross Support Catheters are substantially equivalent to the predicate devices and they will perform in a safe and effective manner when used as indicated.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Spectranetics Corporation
c/o Mr. Michael J. Ryan
Regulatory Affairs Manager
96 Talamine Court
Colorado Springs, CO 80907

Re: K033678
Spectranetics Quick-Cross Support Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (two)
Product Code: DQY
Dated: November 21, 2003
Received: November 25, 2003

Dear Mr. Ryan:

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): K033678

Device Name: Spectranetics Quick-Cross Support Catheter

Indications For Use:

The Spectranetics Quick-Cross Support Catheters are a guidewire exchange and infusion device designed for use in the vascular system. The catheters are intended to support a guidewire during access of the vasculature, allow for exchange of guidewires, and provide a conduit for the delivery of saline solutions or diagnostic contrast agents.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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 Devic

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