K092396

SEP 04 2009

510(k) Summary

Quick-Cross Extreme Support Catheter
Special 510(k) Submission

Spectranetics Corporation requests that the attached "Summary" for the Quick-Cross® Extreme Support Catheters be distributed upon request under the Freedom of Information Act. This report is a summary of the information presented in this 510(k) submission.

Owner/Manufacturer: Spectranetics Corporation
96 Talamine Court
Colorado Springs, CO 80907

Contact Person:

Name	Cheryl Hastings
Title	Regulatory Affairs & Compliance Manager
Office Phone:	719-447-2482
BlackBerry	719-659-1848
Fax	719-447-2040

Date of Summary Preparation: July 31, 2009

Establishment Registration Number: 1721279

Trade Name of Device: Spectranetics Quick Cross® Extreme Support Catheters

Common Name: Support Catheters

Classification Name: Catheters Percutaneous

Class: II

Product Code: DQY

Predicate Devices: Spectranetics Quick Cross® Extreme Support Catheters K082561 and the Spectranetics Quick Cross Support 2 Catheters K072750

Device Description: The Spectranetics Quick-Cross® Extreme Support Catheters are intravascular catheters. These catheters are available in a variety of lengths, diameters and tip configurations. All models have 3 radiopaque markers spaced equally along the distal shaft to aid in estimating geometry within the vascular system. The distal radiopaque marker is positioned within 3 mm of the distal catheter tip. A standard female luer is placed on the proximal end of each model. The catheter is coated with a lubricious, hydrophilic coating on the distal 100cm for catheters with a working length greater than 100cm and 60cm for those with a working length less than 100cm

Indications for Use: Quick-Cross® Extreme Support Catheters are intended to guide and support a guidewire during access of the vasculature, allow for wire exchanges and provide a conduit for the delivery of saline solutions or diagnostic contrast agents.

Intended Use:

Intended Customers

The primary customers are those physicians that perform endovascular treatment of vascular disease, namely Interventional Cardiologists, Interventional Radiologists and Vascular Surgeons who are trained in endovascular procedures.

Intended Patient Population

The intended patient population is those suffering from vascular disease, both coronary and peripheral.

Technological Comparison:

The 0.014" and the 0.018" Quick Cross® Extreme is a smaller lumen version of the previously approved 0.035" Spectranetics Quick-Cross® Extreme (K082561). The products are substantially equivalent with regards to materials, design principles and construction. The 0.014" and the 0.018" Quick Cross® Extreme is also substantially equivalent to the 0.014" and the 0.018" Quick Cross® (K072750) with regards to dimensions, specifications and intended use.

Conclusion:

The0.014" and the 0.018" Quick Cross® Extreme catheters are substantially equivalent to the predicate device the 0.035" Spectranetics Quick-Cross® Extreme (K082561) and substantially equivalent to the Quick Cross® (K072750).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

SEP 04 2009

Ms. Cheryl Hastings
Regulatory Affairs & Compliance Manager
Spectranetics Corporation
9965 Federal Drive
Colorado Springs, CO 80921

Re: K092396
Trade/Device Name: Quick-Cross Extreme Support Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: July 30, 2009
Received: August 5, 2009

Dear Ms. Hastings:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram 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: K092396

Device Name: Quick-Cross® Extreme Support Catheter

Indications for Use:

Quick-Cross® Extreme Support Catheters are intended to guide and support a guidewire during access of the vasculature, allow for wire exchanges and provide a conduit for the delivery of saline solutions or diagnostic contrast agents.

Prescription Use only 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. McNamara

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K092396