510(k) Summary

SUBMITTER INFORMATION

DEC 0 4 2007

A. Company Name: Spectranetics Corporation, Inc.

B. Company Address: 96 Talamine Court
Colorado Springs, Colorado 80907

C. Company Phone: 719-633-8333 / 1-800-633-0960

D. Company Facsimile: 719-447-2040

E. Contact Person: Michael K. Handley
Director, Global Regulatory Affairs

DEVICE IDENTIFICATION

A. Device Trade Name: Spectranetics Quick-Cross Support^2 Catheter

B. Device Common Name: Support Catheter

C. Classification Name: Catheter, Percutaneous

D. Device Class: Class II (per 21 CFR 870.1330)

E. Device Code: DQY

CLAIMED EQUIVALENCE

Spectranetics Quick-Cross Support^2 Catheter Models: 0.014" (K991059), 0.035" (K022138), and modified 0.014"/0.035" (K033678)

DEVICE DESCRIPTION

Model number	Wire compatibility	Sheath Compatibility	Length
518-065	0.014" diameter	5Fr	150 cm
518-066	0.035" diameter	5Fr	65 cm

Model number 518-065 has a shaft of varying stiffness with a proximal shaft diameter of 3 Fr. Tapering to a distal shaft diameter of 1.9 Fr and is compatible with a 0.014 inch or smaller guide wire.

Model number 518-066 has a shaft of varying stiffness with a proximal shaft diameter of 4.8 Fr. Tapering to a distal shaft diameter of 3.7 Fr and is compatible with a 0.035 inch or smaller guide wire.

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. The support catheters are single-use and provided in sterile packaging.

INTENDED USE

The Spectranetics Quick-Cross Support^2 Catheter is designed for use in the vascular system. The catheters are intended to support a guide wire during access to the vasculature, allow for exchange of guide wires, and provide a conduit for the delivery of saline solutions or diagnostic contrast agents.

IDENTIFICATION OF PREDICATE DEVICES

Spectranetics Quick-Cross Support^2 Catheters are equivalent to the Spectranetics Quick-Cross Support^2 Catheters (K033678, K022138, and K991059) with regard to materials, basic design principles, construction, specifications, intended use and performance. Both are examples of a support catheter for guide wires, a common and familiar tool of cardiovascular interventionist.

COMPARISON TO PREDICATE DEVICES

Comparative laboratory testing was conducted to assess physical dimensions, infusion rates and burst pressure. Test results show that the Spectranetics Quick-Cross Support^2 Catheters are equivalent to the predicate devices (unmodified Quick-Cross Support^2 Catheters) with regard to safety, effectiveness, indication and performance.

BIOCOMPATIBILITY, STERILIZATION, PACKAGING, AND BENCH TESTING

Quick-Cross Support^2 Catheters are built from the same components and materials of construction as the unmodified Quick-Cross Support^2 Catheters, already-marketed products. Therefore, biocompatibility of the finished Quick-Cross Support^2 Catheters utilizing identical component materials have been previously confirmed in conformance with ISO 10993-1:2003, Biological Evaluation of Medical Devices. Device integrity and functionality were qualified and/or validated using samples produced under routine manufacturing conditions. An internal company protocol was prepared and executed in conformance with ANSI/AAMI/ISO 11135:1994, Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization. All Quick-Cross Support^2 Catheters models meet or exceed both Spectranetics in-house requirements, and requirements listed in ISO 10555-1, Sterile, Single-use Intravascular Catheters – Part 1: General Requirements. Package integrity was initially validated in conjunction with sterilization studies.

TECHNICOLOGICAL CHARACTERISTICS

The Spectranetics Quick-Cross Support^2 Catheters have the same technical characteristics as the predicate devices, the unmodified Quick-Cross Support^2 Catheters. Both are constructed from HDPE extruded tubing, HDPE molded luers, and platinum/iridium bands. All support catheters have a 0.068 inch maximum diameter with the capacity to accommodate 0.014" – 0.035" diameter guide wires depending on the model (see table below).

Model number	Wire compatibility	Sheath Compatibility	Length
518-065	0.014" diameter	5Fr	150 cm
518-066	0.035" diameter	5Fr	65 cm

CONCLUSION

The Spectranetics Quick-Cross Support^2 Catheters are substantially equivalent to the unmodified Quick-Cross Support^2 Catheters.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 4 2007

The Spectranetics Corporation
c/o Mr. Michael K. Handley
Director Global Regulatory Affairs
96 Talamine, CT.
Colorado Springs, CO 80907

Re: K072750
Trade/Device Name: Quick Cross Support 2 Catheters
Regulation Number: 21 CFR 870.1250
Regulation Name: Support Catheter
Regulatory Class: II (two)
Product Code: DQY
Dated: November 8, 2007
Received: November 14, 2007

Dear Mr. Handley:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Richner

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

Enclosure

8. Statement of Indication for Use K072750

Device Name: Quick-Cross® Support^2 Catheter

Indications for Use

The Spectranetics Quick-Cross Support^2 Catheters are designed for use in the vascular system. The catheters are intended to support a guide wire during access to the vasculature, allow for exchange of guide wires, and provide a conduit for the delivery of saline solutions or diagnostic contrast agents.

Prescription Use **XXXX** 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. Bachner
(Division Sign-Off)
Division of Cardiovascular Devices

510(K) Number K072750