510(k) Summary

SUBMITTER INFORMATION

DEC 10 2008

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
Vice President, Global Regulatory Affairs & Compliance

DEVICE IDENTIFICATION

A. Device Trade Name: Spectranetics Quick-Cross Extreme Support Catheters
B. Device Common Name: Support Catheters
C. Classification Name: Catheter, Percutaneous
D. Device Class: Class II (per 21 CFR 870.1330)
E. Device Code: DQY

CLAIMED EQUIVALENCE

Quick-Cross® Support^2 Catheters
(K991059, K022138, K033678, and K072750)

4Fr Terumo RadiFocus Optitorque (K992051)

DEVICE DESCRIPTION

Specifications:

Model (Ref.)	Size	Max. (OD) Outer Diameter	Working Length	Guide Wire Compatability	*Max Pressure psi (kPa)	Tip Shape
518-076	4 Fr	0.059" / 1.50 mm	65 cm	.035"	500 (3447)	Straight
518-078	4 Fr	0.059" / 1.50 mm	90 cm	.035"	500 (3447)	Straight
518-080	4 Fr	0.059" / 1.50 mm	135 cm	.035"	500 (3447)	Straight
518-082	4 Fr	0.059" / 1.50 mm	150 cm	.035"	500 (3447)	Straight
518-077	4 Fr	0.059" / 1.50 mm	65 cm	.035"	500 (3447)	Angled
518-079	4 Fr	0.059" / 1.50 mm	90 cm	.035"	500 (3447)	Angled
518-081	4 Fr	0.059" / 1.50 mm	135 cm	.035"	500 (3447)	Angled
518-083	4 Fr	0.059" / 1.50 mm	150 cm	.035"	500 (3447)	Angled

*** 75/25 Optiray 320 Contrast Sterile Saline**

All models have 3 radiopaque markers spaced equally along the distal shaft to aid in estimating geometry within the vascular system. The most 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. 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

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.

IDENTIFICATION OF PREDICATE DEVICES

Spectranetics Quick-Cross Extreme Support Catheters are equivalent to the Terumo 4Fr Radifocus Optitorque Angiographic Catheter (K992051), marketed as the 5Fr Radifocus Glidecath, with regard to materials, basic design principles, construction, specifications, intended use and performance. It is also equivalent to the Spectranetics Quick-Cross Support^2 Catheter 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 Extreme Support Catheters are equivalent to the predicate devices with regard to safety, effectiveness, indication and performance.

BIOCOMPATIBILITY, STERILIZATION, PACKAGING, AND BENCH TESTING

Quick-Cross Extreme Support Catheters are built from the same components and materials of construction as the predicate devices, already-marketed products. Biocompatibility of the finished Quick-Cross Extreme Support Catheters utilizing identical component materials have been 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 Extreme Support 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.

TECHNILOGICAL CHARACTERISTICS

The Spectranetics Quick-Cross Extreme Support Catheters have the same technical characteristics as the Terumo 4Fr Radifocus Optitorque (GlideCath) and the Quick-Cross Support^2 Catheters, the predicate devices. Both devices feature a stainless steel braided shaft for aided support and torque response and a tapered tip. All support catheters have a 0.066 inch diameter with the capacity to accommodate up to 0.035" diameter guidewires depending on the model.

CONCLUSION

The Spectranetics Quick-Cross Extreme Catheters are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 10 2008

Spectranetics Corporation, Inc.
c/o Mr. Michael K. Handley
Vice President
Global Regulatory Affairs & Compliance
9965 Federal Drive
Colorado Springs, CO 80921

Re: K082561
Spectranetics Quick-Cross® Extreme Support Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: November 18, 2008
Received: November 19, 2008

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 Biometrics' (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,

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

Enclosure

510(k) #: K082561

Statement of Indication for Use

Device Name: Spectranetics Quick-Cross® Extreme Support Catheters

Indications for Use

Quick-Cross® Extreme Support Catheters are intended to guide and support a guide wire 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 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)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K082561