K090913

510(k) SUMMARY OF SUBSTANTIAL EQUIVALENCE

MAY - 4 2009

Proprietary Name:	Cross-Pilot™ Turbo elite® Support Catheter
Common Name:	Support Catheter
Classification Name:	Percutaneous Catheter
Device Classification:	Class II
Product Classification and Code:	21 CFR 870.1250, DQY
Classification Panel:	Cardiovascular Devices
Establishment Registration Number:	3007284006
Contact Person:	Brandon Hansen Regulatory Affairs Spectranetics Corporation 9965 Federal Drive Colorado Springs, CO 80921 Telephone: (719) 447-2385 Facsimile: (719) 447-2040 E-mail: *brandon.hansen@spnc.com*

Performance Standards

Performance standards do not currently exist for these devices. None established under Section 514.

(D
Div
510(k) Number K090913

Device Description

The Spectranetics Cross-Pilot™ Turbo Elite® Support Catheters are intravascular catheters. These catheters are available in a variety of lengths 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.

Indication for Use

Cross-Pilot™ Turbo elite® Support Catheters are intended to guide and support Spectranetics laser catheters during access of the vasculature and provide a conduit for the delivery of saline solution or diagnostic contrast agents.

Substantially Equivalent Devices

In Spectranetics' opinion, the Cross-Pilot™ Turbo elite® Support Catheter is believed to be substantially equivalent to the following predicate device currently in interstate commerce with respect to comparable features, materials of construction and intended use.

- Cross-Pilot™ Turbo elite® Support Catheter (Spectranetics Corp., Colorado Springs, CO) – K082559

Labeling, packaging, materials and sterilization of the Cross-Pilot™ Turbo elite® Support Catheter has not changed from that of the predicate devices listed above.

Summary of Studies

Spectranetics performed device functional testing to support that the Cross-Pilot™ Turbo elite® Support Catheter is equivalent to the predicate device. All device functional test results for the Cross-Pilot™ Turbo elite® Support Catheter met specified requirements.

Conclusion (Statement of Equivalence)

Through data and information presented, numerous similarities support a determination of substantial equivalence, and therefore market clearance of the Spectranetics Cross-Pilot™ Turbo elite® Support Catheter through this Special 510(k) Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 4 2009

Spectranetics Corporation
c/o Mr. Brandon Hansen
Manager, Global Regulatory Affairs
9965 Federal Drive
Colorado Springs, CO 80921

Re: K090913
Cross-Pilot Turbo Elite Support Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: March 31, 2009
Received: April 1, 2009

Dear Mr. Hansen:

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 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 the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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

INDICATION FOR USE

510(k) Number (if known): K090913

Device Name: Cross-Pilot™ Turbo elite® Support Catheter

Indication For Use: Cross-Pilot™ Turbo elite® Support Catheters are intended to guide and support Spectranetics laser catheters during access of the vasculature and provide a conduit for the delivery of saline solution or diagnostic contrast agents.

Prescription Use X AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C))

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Bruce Kramer

(Division Sign-Off) 5/5/09

Division of Cardiovascular Devices

510(k) Number K090913