NOV 1 6 1999

Spectranetics

K991059

BRILLIANCE IN INTERVENTIONAL THERAPY

Submitted By:
Adrian E. Elfe, CQM, RAC
Vice President, Quality Assurance and Regulatory Affairs
Spectranetics Corporation
96 Talamine Court
Colorado Springs, CO 80907
Signature and Date: Adrian E. Elfe 19 Oct 99

510(k) Summary

Device Trade Name: The device trade name is Spectranetics Support Catheter. The generic name for this device is percutaneous catheter.

The Spectranetics Support Catheter is a coronary intravascular catheter used to support a guidewire, to assist in guidewire exchange or placement in distal vessels, and to provide a conduit for the delivery of saline solutions or diagnostic contrast agents. It is designed for patients needing vascular intervention. Predicate devices of this type with similar intended uses have been classified into Class II.

Substantial Equivalence:

This product is similar in design, composition, and function to the Medtronic Buchbinder Transfer Catheters, 510(k) K935425.

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA1990 and 21 CFR 807.92.

The Spectranetics Support Catheters are similar in basic design, construction, mechanical safety, indications, target population, risk analysis, performance and materials to the predicate device. Spectranetics New Product Introduction procedure has been faithfully followed in concert with the quality systems regulations for new product introduction. The design validation protocols and the Design Failure Mode, Effect and Criticality Analysis (FMECA), addressed all known risks associated with the device including tensile strength, bond joints, tracking, visibility, flow rate, wire movement, sterility and biocompatibility including hemolysis, MEM cytotoxicity and dermal sensitization. Testing performed for the Spectranetics Support Catheter provides reasonable assurance that the devices 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

NOV 16 1999

Mr. Michael J. Quinn
Director of Regulatory Affairs
Spectranetics Corporation
96 Talamine Court
Colorado Springs, CO 80907-5186

Re: K991059
Trade Name: Spectranetics Support Catheter
Regulatory Class: II
Product Code: DQY
Dated: October 21, 1999
Received: October 22, 1999

Dear Mr. Quinn:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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.

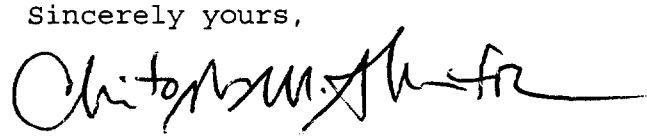
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation

you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,



Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular,
Respiratory and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Applicant: Spectranetics Corporation
96 Talamine Court
Colorado Springs, CO 80907

510(k): _____

Device Name: Spectranetics Support Catheter

Statement of Indications for Use
Spectranetics Support Catheter

The Spectranetics Support Catheter is a coronary intravascular catheter used to support a guidewire, to assist in guidewire exchange or placement in distal vessels, and to provide a conduit for the delivery of saline solutions or diagnostic contrast agents. It is designed for patients needing vascular intervention.

Christopher M. Ahn for Witten

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K991059