K022138

Spectranetics
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SEP 23 2002

Premarket Notification 510(k) Summary

Submitted By:
Michael J. Ryan
RA Manager
Spectranetics Corporation
96 Talamine Court
Colorado Springs, CO 80907
Signature and Date: 1 July 2002

Device Trade Name:	Spectranetics 0.035" Support Catheter.
Common Name:	Intravascular Catheter
Classification Name:	Percutaneous Catheter, CFR 870.1250

Device Description:

The Spectranetics Support Catheters are intravascular catheters, available in 3 models. Model 518-016 is a 0.014 inch guidewire compatible, 3.0 French (Fr.) outside diameter catheter. Model 518-017 is a 0.018 inch guidewire compatible, 3.4 Fr. outer diameter catheter. The new device, Model 518-028 is a 0.035 inch guidewire compatible, 4.8 Fr. outer diameter catheter. All models have a working length of 135 centimeters. All models have a radiopaque marker 2-3 mm from its 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.

Indications for Use:

The Spectranetics Support Catheters are designed for use in the vascular system. The catheters are intended to support a guidewire during access of the vasculature, allow for exchange of guidewires, and provide a conduit for the delivery of saline solutions or diagnostic contrast agents.

Substantial Equivalence:

This product is substantially equivalent in design, composition, function, and intended use to the Spectranetics Support Catheter, 510(k) K991059, November 6, 1999, and the Medtronic Buchbinder Transfer Catheter, 510(k) K935425.

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Technological Characteristics & Nonclinical Testing Summary:	The Spectranetics Support Catheters are similar in design, construction, indications, target population, risk analysis, performance and materials to the predicate devices, the Spectranetics 0.014" and 0.018" Support Catheters, K991059. Spectranetics New Production Introduction procedure has been used in concert with the Quality System Regulations for the introduction of the 0.035" Support Catheter. The design validation protocols and risk analysis addressed all known aspects of the device including tensile strength, functionality, visibility, flow rate, sterility, and biocompatibility. Testing performed for the Spectranetics Support Catheter provides reasonable assurance that the device will perform in a safe and effective manner when used as indicated The Spectranetics 0.014", 0.018", and the new 0.035" Support Catheters are similar in the indications for use as the Medtronic Buchbinder Catheter (K935425), the previous predicate device for the Spectranetics 0.014" and 0.018" Support Catheter, K991059.
Conclusions:	The results of the testing demonstrate that the Spectranetics 0.035" Support Catheter is substantially equivalent to the predicate devices and it 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

SEP 23 2002

Mr. Michael J. Ryan
RA Manager
Spectranetics Corporation
96 Talamine Court
Colorado Springs, CO 80907

Re: K022138
Spectranetics 0.035" Support Catheter, Model 518-028
Regulation Number: 870.1250
Regulation Name: Percutaneous catheter.
Regulatory Class: Class II (two)
Product Code: 74 DQY
Dated: July 1, 2002
Received: July 2, 2002

Dear Mr. Ryan:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

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

Enclosure

K022138

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

510(k): _____

Device Name: Spectranetics 0.014", 0.018", and 0.035" Support Catheters

Statement of Indications for Use

The Spectranetics Support Catheters are designed for use in the vascular system. The catheters are intended to support a guidewire during access of the vasculature, allow for exchange of guidewires, and provide a conduit for the delivery of saline solutions or diagnostic contrast agents.

Division of Cardiovascular & Respiratory Devices
510(k) Number K022138