



Food and Drug Administration
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May 31, 2016

The Spectranetics Corporation
Ms. Kimberley Kline
Senior Manager, Regulatory Affairs
9965 Federal Drive
Colorado Springs, CO 80921

Re: K150634

Trade/Device Name: AngioSculpt PTA Scoring Balloon Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: PNO
Dated: March 10, 2015
Received: March 11, 2015

Dear Ms. Kline,

This letter corrects our substantially equivalent letter of April 8, 2015.

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 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Misti L. Malone -S

for Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K150634

Device Name

AngioSculpt PTA Scoring Balloon Catheter, 7.0/8.0mm x 40mm

Indications for Use (Describe)

For dilatation of lesions in the iliac, femoral, ilio-femoral, popliteal, infra popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. Not for use in the coronary or neuro-vasculature.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)



510(k) Summary

This 510(k) summary was prepared in accordance with 21 CFR 807.92

Prepared on *March 10, 2015*

510(k) Submitter / Holder: Spectranetics
5055 Brandin Court
Fremont, CA 94538
Establishment Registration No: 3005462046

Contact: Kimberley Kline
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Subject Device

Device Trade Name: AngioSculpt® PTA Scoring Balloon Catheter
Device Common Name: Angioplasty catheter
Device Class: II
Classification Regulation: 21 CFR 870.1250
Regulation Description: Percutaneous catheter
Product Code: LIT
510(k) Type: Special
Model Numbers: 2332, 2333, 2334

Predicate Device

The AngioSculpt PTA Scoring Balloon Catheter was compared to the following legally marketed predicate device:

Trade Name/510(k) Number: AngioSculpt® PTA Scoring Balloon Catheters
K133998 4.0-6.0x200mm (137cm length)

Manufacturer: Spectranetics
Device Common Name: Angioplasty catheter

Trade Name/510(k) Number AngioSculpt® PTA Scoring Balloon Catheters
K091966 6.0x40mm (50,90 and 137cm)

Manufacturer: Spectranetics
Device Common Name: Angioplasty catheter

Device Description

The 7.0/8.0mm x 40mm AngioSculpt PTA Scoring Balloon Catheters are comprised of a conventional balloon catheter that incorporates a nitinol scoring element over the balloon. The balloon is designed to expand to a specified diameter at a specified pressure. The catheter has radiopaque markers to aid in positioning of the balloon in the stenosis. The catheter has two lumens; one lumen is used for inflation of the balloon with contrast medium; the other lumen permits the use of a guide wire to facilitate advancement of the catheter to and through the stenosis to be dilated. The product is provided in the over-the-wire (OTW) delivery platform. The catheters have a sheath compatibility of 6F and guidewire compatibility of 0.018". The catheter is single-use only and provided sterile to the user.

Intended and Indications for Use

The AngioSculpt PTA Scoring Balloon Catheter is intended for dilatation of lesions in the iliac, femoral, ilio-femoral, popliteal, infra popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. Not for use in the coronary or neuro-vasculature.

Technological Characteristics

The 7.0/8.0mm x 40mm AngioSculpt PTA Scoring Balloon catheters are equivalent to the currently cleared and marketed 4.0-6.0mm x 40mm and 200mm AngioSculpt family of devices because they share substantially the same; indications for use, device operation, material type, basic design configuration and overall technical and functional capabilities.

Performance Data

The following testing was conducted to validate and verify that the subject device was substantially equivalent to the predicate devices

Design Verification and Validation Testing

- Catheter Diameter and Balloon Profile
- Balloon Preparation, Deployment and Retraction
- Rated Burst Pressure (RBP)
- Device Fatigue
- Balloon Compliance (Diameter vs. Pressure)
- Balloon Inflation/ Deflation Time
- Bond (Tensile) Strength
- Tip Pull Strength
- Catheter Diameter and Balloon Profile (post deflation)



- Catheter Flexibility and Kink
- Torque Strength
- Radiopacity
- Pushability, Trackability and Secure Edges
- Freedom from Stent Interference
- Guide Wire Compatibility
- Catheter Effective Length
- Catheter Surface Appearance
- Luer Compatibility
- Focal Force

Sterilization

- Product adoption equivalency per AAMI TIR:28 2009

Biocompatibility

The materials used in the subject device pose no greater significant biocompatibility challenge than the current AngioSculpt products. Biocompatibility test results of the currently marketed product have previously been performed and are biocompatible. Cytotoxicity, Sensitization, Irritation, Systemic Toxicity, Hemocompatibility, and Genotoxicity tests were conducted according to current standards (e.g. ISO 10993-5). Due to similarities in design, manufacturing processes, sterilization, intended use, and device categorization, the combined biocompatibility test results of predicate product can be used to confirm the biocompatibility of the subject device.

Preclinical and Clinical Data

Preclinical and clinical data were not required to demonstrate substantial equivalence. The design characteristics of the subject device are similar to the predicate. The design verification and validation test results demonstrated that the subject device is as safe and clinically effective as the predicate device.

Substantial Equivalence

Based on the similarities in design between the subject and predicate devices, and the performance testing performed, the subject AngioSculpt PTA Scoring Balloon Catheter, 7.0/8.0mm x 40mm, 50,90,137cm is substantially equivalent to the predicates, AngioSculpt 4.0- 6.0x200mm (50, 90, 137cm length) devices cleared under K133998 and the 4.0-6.0 x 40mm AngioSculpt devices cleared under K091966.