DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 13, 2017

Cagent Vascular, LLC
Ms. Carol A. Burns
President and CEO
150 Strafford Avenue #315
Wayne, PA 19087

Re: K163380
Trade/Device Name: Serranator Alto PTA Serration Balloon Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: PNO
Dated: December 1, 2016
Received: December 2, 2016

Dear Ms. Burns:

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. 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" (21 CFR 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,

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163380

Device Name
Serranator Alto PTA Serration Balloon Catheter

Indications for Use *(Describe)*
The Serranator™ Alto PTA Serration Balloon Catheter is intended for dilatation of lesions in the iliac, femoral, ilio-femoral, and popliteal 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Cagent Vascular, LLC
150 Strafford Avenue #315
Wayne, PA 19087

510(k) Summary
[as required by 21 CFR 807.92(c)]

***Serranator*™ Alto PTA Serration Balloon Catheter**
Cagent Vascular, LLC

510(k) __K163380___

DATE PREPARED	November 28, 2016
APPLICANT INFORMATION	Carol Burns/President & CEO 150 Strafford Avenue #315 Wayne, PA 19087
CONTACT INFORMATION	Carol A. Burns, President and CEO Phone: 610-688-2006 Email: cburns@cagentvascular.com
TRADE NAME	*Serranator*™ Alto PTA Serration Balloon Catheter
DEVICE CLASSIFICATION	Class 2 per 21 CFR §870.1250
CLASSIFICATION NAME	Percutaneous Catheter
PRODUCT CODE	PNO
PREDICATE DEVICE	AngioSculpt® Scoring Balloon Catheter (K122685)

INTENDED USE/INDICATIONS FOR USE

The *Serranator*™ Alto PTA Serration Balloon Catheter is intended for dilatation of lesions in the iliac, femoral, ilio-femoral, popliteal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. Not for use in the coronary or neuro-vasculature.

DEVICE DESCRIPTION

The *Serranator*™ Alto PTA Serration Balloon Catheter is an over-the-wire (OTW) balloon dilatation catheter designed to perform percutaneous transluminal angioplasty (PTA) for peripheral vasculature as described in the Indications for Use statement. The *Serranator*™ has a nylon semi-compliant balloon with four embedded external metal strips, or scoring elements. The scoring elements are designed to create linear, interrupted scoring along the endoluminal surface that occurs during balloon angioplasty.

COMPARISON WITH PREDICATE DEVICE

A comparison of the *Serranator*™ Alto PTA Serration Balloon Catheter and predicate device shows that the technological characteristics such as the components, design, materials, sterilization method, shelf life and operating principle of the *Serranator*™ are identical or similar to the currently marketed AngioSculpt® Scoring Balloon Catheter , the predicate device.

The intended use of the Subject Device and its primary predicate is identical. The indications for use of the *Serranator*™ Alto PTA Serration Balloon Catheter are similar (a subset) to that of the predicate device.

Item		Subject Device	Predicate Device
Name		*Serranator*™ Alto PTA Serration Balloon Catheter	AngioSculpt® Scoring Balloon Catheter
Manufacturer		Cagent Vascular	Spectranetics
510(k) Number		Current Application	K122685
Intended Use		Dilatation of lesions in the iliac, femoral, ilio-femoral, and popliteal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. Not for use in the coronary or neuro-vasculature.	Dilatation of lesions in the iliac, femoral, ilio-femoral, 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.
Target Body Location		Peripheral	Peripheral
Principle of Operation		Balloon dilatation with interrupted, axial scoring	Balloon dilatation with continuous helical scoring
Design	**Platform**	Over-The-Wire (OTW)	Over-The-Wire (OTW)
	Maximum OD	6 Fr	6 Fr
	Effective Length [cm]	150	137
Balloon Characteristic	**Balloon Diameters [mm]**	4.0, 5.0, and 6.0	3.5 through 6.0
	Balloon lengths [mm]	40, 80, and 120	40 through 200

NON CLINICAL TESTING / PERFORMANCE DATA

Bench testing in accordance with FDA guidance[1], ASTM and ISO standards was performed on sterile, unaged (Time Zero) and accelerated aged (Time Aged) test samples of *Serranator*™ Alto PTA Serration Balloon Catheter.

[1] Guidance for Industry and FDA Staff - Non-Clinical Engineering Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems, April 2010. Only the sections associated with Delivery Systems were applied to *Serranator*.

The following testing/assessments were performed:

- Shipping, environmental stresses
- Flex/Kink
- Peel Strength
- Visual Inspection
- Particulates
- Delivery, Deployment. Retraction
- Fatigue
- Rated Burst/Compliance
- Torsion
- Corrosion
- Tensile Test of Joints
- Lubricious Coating Integrity

The non-clinical testing results demonstrated that the *Serranator*™ met all acceptance criteria. Performance data demonstrate that the device functions as intended.

BIOCOMPATIBILITY

FDA guidance document *Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" Draft Guidance for Industry and Food and Drug Administration Staff, April 23, 2013*, ISO-10993 *Biological Evaluation of Medical Devices Part 1: Evaluation and Testing*, and ISO-10993 *Biological Evaluation of Medical Devices Part 12: Sample Preparation and Reference Materials* were followed in selecting and conducting the biocompatibility testing of the *Serranator*™ Alto PTA Serration Balloon Catheter.

Biocompatibility testing was conducted on sterile, finished devices manufactured using the manufacturing processes which will be used for the cleared devices. All testing passed the required acceptance criteria and the product is biocompatible for human use.

ANIMAL STUDIES

Peripheral vessels in a porcine model were treated with a *Serranator*™ Alto PTA Serration Balloon Catheter or control, AngioSculpt® PTA Scoring Balloon Catheter.

Morphometric measurements were similar between *Serranator*™ and AngioSculpt. Neointimal areas, thickness and percent stenosis were minimal and similar in both groups.

CADAVER STUDIES

Cadaver testing was performed comparing the *Serranator*™ to the predicate device and was found to have similar performance.

CONCLUSION

The *Serranator*™ Alto PTA Serration Balloon Catheter has identical intended use and similar technological characteristics such as components, design, materials, sterilization method, shelf life and operating principles as the predicate and reference devices. Performance data demonstrates that the device functions as intended.

Data presented in this 510(k) Submission support that the *Serranator*™ Alto PTA Serration Balloon Catheter is substantially equivalent to the predicate device AngioSculpt® PTA Scoring Balloon Catheter.