April 15, 2020

Cagent Vascular, LLC
Carol Burns
CEO
150 Strafford Avenue #315
Wayne, Pennsylvania 19087

Re: K193181
Trade/Device Name: Serranator PTA Serration Balloon Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: PNO
Dated: March 18, 2020
Received: March 19, 2020

Dear Carol 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K193181

Device Name
Serranator® PTA Serration Balloon Catheter

Indications for Use *(Describe)*
The Serranator® PTA Serration Balloon Catheter is intended for dilatation of lesions in infrapopliteal arteries. 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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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*® PTA Serration Balloon Catheter**
**Cagent Vascular, LLC**

## 510(k): K193181

| | |
|---|---|
| **DATE PREPARED** | April 15, 2020 |
| **APPLICANT INFORMATION** | Carol Burns/President & CEO<br>150 Strafford Avenue #315<br>Wayne, PA 19087 |
| **CONTACT INFORMATION** | Carol A. Burns, President and CEO<br>Phone: (610) 688-2006<br>Fax: (610) 688-2667<br>Email: cburns@cagentvascular.com |
| **TRADE NAME** | *Serranator*® PTA Serration Balloon Catheter |
| **DEVICE CLASSIFICATION** | Class 2 per 21 CFR §870.1250 |
| **CLASSIFICATION NAME** | Percutaneous Catheter |
| **PRODUCT CODE** | PNO |
| **PREDICATE DEVICES** | Predicate Device:<br>*AngioSculpt*® PTA Scoring Balloon Catheter (K142983)<br>Reference Device:<br>*Serranator*® Alto PTA Serration Balloon Catheter (K163380) |

## 5.1 Intended Use/Indications for Use

The *Serranator*® PTA Serration Balloon Catheter is intended for dilatation of lesions in infrapopliteal arteries. Not for use in the coronary or neuro-vasculature.

## 5.2 Device Description

The *Serranator*® PTA Serration Balloon Catheter is an over-the-wire (OTW) balloon dilatation catheter designed to perform percutaneous transluminal angioplasty (PTA) for peripheral indications as described in the Indication for Use statement. The *Serranator*® has a nylon semi-compliant balloon with three embedded external metal strips or scoring elements. The unique scoring elements are serrated, designed to modify the plaque by creating linear, interrupted scoring along the endoluminal surface. This occurs during balloon inflation and is designed to aid arterial expansion.

## 5.3 Comparison with Predicate Devices

A comparison of the *Serranator*® PTA Serration Balloon Catheter (*Serranator*) and predicate device shows that the technological characteristics such as the components, design, materials, sterilization method, and operating principle of the *Serranator* are identical or similar to the currently marketed *AngioSculpt*® PTA Scoring Balloon Catheter (*AngioSculpt*) (K142983) and the *Serranator*® Alto PTA Serration Balloon Catheter (*Serranator Alto*) (K163380), predicate and reference devices respectively.

The technological differences are that the scoring elements of *Serranator*® are interrupted, rather than a continuous metal configuration such as the *AngioSculpt* device. The unique scoring elements are serrated, designed to create linear, interrupted scoring along the endoluminal surface.

The intended use of the subject device and the predicate device is similar. The indications for use of the *Serranator*® PTA Serration Balloon Catheter are similar to that of the Serranator Alto reference device.

## 5.4 Non-Clinical Testing/Performance

The *Serranator*® PTA Serration Balloon Catheter has been tested through the design verification activities to demonstrate that the device meets design input requirements. The following tests were conducted and passed all requirements (see Table 3.1 below).

**Table: 5.1 Summary of Non-Clinical/Performance Testing**

| Test | Result |
|---|---|
| **Shipping, environmental stresses** | Pass |
| **Flex/Kink** | Pass |
| **Visual Inspection** | Pass |
| **Delivery, Deployment, Retraction** | Pass |
| **Fatigue** | Pass |
| **Rated Burst/Compliance** | Pass |
| **Torsion** | Pass |
| **Corrosion** | Pass |
| **Tensile Test of Joints** | Pass |

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*® PTA Serration Balloon Catheter.

The non-clinical testing demonstrated that the *Serranator*® met all acceptance criteria. Performance data demonstrate that the device functions as intended and has an acceptable safety and effectiveness profile.

## 5.5 Biocompatibility

FDA guidance document *Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" Guidance for Industry and Food and Drug Administration Staff, June 16, 2016*, 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* 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. Testing confirmed that the *Serranator* is non-cytotoxic, non-sensitizing, non-irritating, not systemically toxic, non-thrombogenic, and non-hemolytic.

[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*.

Table 3.2 provides a list of the various tests completed and passed.

**Table 5.2: Biocompatibility Tests**

| Test | Results |
|---|---|
| **Cytotoxicity** | Pass |
| **Sensitization** | Pass |
| **Irritation** | Pass |
| **Systemic Toxicity (acute)** | Pass |
| **Pyrogenicity** | Pass |
| **Hemocompatibility** | Pass |
| | Pass |
| | Pass |

In addition to the tests indicated in Table 5.2, thrombogenicity evaluation was conducted as part of the Acute Porcine Study.

### 5.6 Animal Studies

An animal study was performed to assess usability, performance and acute thromboresistance of the *Serranator*® PTA Serration Balloon Catheter in swine peripheral arteries. In accordance with general FDA animal study guidelines and ISO-10993-4 methodology, a total of two porcine test subjects were used for assessment. No adverse events including filling defects, dissections, thrombus formation or perforations occurred in this study.

### 5.7 Cadaver Studies

A diseased cadaver study was not performed using the Serranator® PTA Serration Balloon Catheter (Serranator) as this testing was conducted in the reference device, the Serranator® Alto PTA Serration Balloon Catheter (Serranator Alto) submission (K163380). The results between the subject device and the Serranator Alto (reference) were not expected to differ as both devices have the same function, design and mechanism of action.

A cadaver artery assessment was performed to determine the medial thickness of non-diseased infrapopliteal arteries. These data were used to determine an appropriate strip height for safety. Arteries assessed showed minimal atherosclerotic disease ranging from mild disease to no calcification. Average medial thickness varied significantly between popliteal, anterior tibial, posterior tibial, tibial-peroneal, and peroneal sections.

## 5.7 Conclusion

The *Serranator*® PTA Serration Balloon Catheter has similar intended use and similar technological characteristics such as components, design, materials, sterilization method, 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*® PTA Serration Balloon Catheter is substantially equivalent to the predicate *AngioSculpt*® PTA Scoring Balloon Catheter and reference *Serranator*® Alto PTA Serration Balloon Catheter.