December 15, 2021

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

Re: K213728
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: November 24, 2021
Received: November 26, 2021

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213728

Device Name
Serranator® PTA Serration Balloon Catheter

Indications for Use *(Describe)*
The Serranator® PTA Serration Balloon Catheter is intended for dilatation of lesions in the iliac, femoral, iliofemoral, and popliteal arteries 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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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

Serranator® PTA Serration Balloon Catheter
510(k) K213728

DATE PREPARED:	November 24, 2021
APPLICANT:	Carol Burns/ President & CEO 150 Strafford Avenue, #315 Wayne, PA 19087
CONTACT:	Carol A. Burns, President and CEO Phone: (610) 688-2006 Fax: (610) 688-2667 Email: cburns@cagentvascular.com
TRADE NAME:	Serranator® PTA Serration Balloon Catheter
COMMON NAME:	Percutaneous Catheter
CLASSIFICATION REGULATION:	21CFR 870.1250
DEVICE CLASS:	Class II
PANEL CODE:	PNO
PREDICATE DEVICE:	K163380
REFERENCE DEVICE:	K203437

INTENDED USE/INDICATIONS FOR USE:

The Serranator® PTA Serration Balloon Catheter is intended for dilatation of lesions in the iliac, femoral, iliofemoral, 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.

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 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.

COMPARISON WITH PREDICATE AND REFERENCE DEVICES:

A detailed comparison of the subject device (Serranator) and the predicate device (K163380) along with the reference device K203437 is shown in the table below demonstrates that the technological characteristics of the subject device such as components, design, sterilization method, shelf life and operating principle are identical or similar to the predicate device (K163380).

Table 1. Comparison with Predicate Device:

	Subject Device	**Predicate Device** *Serranator Alto[1] PTA Serration Balloon Catheter* **(Not Commercialized)**	**Reference Device** *Serranator PTA Serration Balloon Catheter* **(Commercialized)**
Device Name	Serranator® PTA Serration Balloon Catheter	Same	Same
Manufacturer	Cagent Vascular, Inc.	Cagent Vascular, Inc.	Cagent Vascular, Inc.
510(k)	-	K163380	K203437
Intended Use/Indication for Use	*The Serranator® PTA Serration Balloon Catheter is intended for dilatation of lesions in the iliac, femoral, iliofemoral, and popliteal, arteries for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. Not for use in the coronary or neuro-vasculature.*	*The Serranator® Alto PTA Serration Balloon Catheter is intended for dilatation of lesions in the iliac, femoral, iliofemoral, 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.*	*The Serranator® PTA Serration Balloon Catheter is intended for dilatation of lesions in infrapopliteal arteries. Not for use in the coronary or neuro-vasculature.*
Regulation	21CFR870.1250	21CFR870.1250	21CFR870.1250
Regulation Name	Percutaneous catheter	Percutaneous catheter	Percutaneous catheter
Regulation Class	Class II	Class II	Class II
Product Code	PNO	PNO	PNO
Prescription/OTC	Prescription	Prescription	Prescription
Catheter Design	OTW	OTW	OTW
Balloon diameter (mm)	4.0, 5.0, 6.0	4.0, 5.0, 6.0	2.5, 3.0, 3.5
Balloon length (mm)	40, 120	40, 80, 120	40, 80, 120
Number of Strips	4	4	3
Strip material	Stainless Steel	Stainless Steel	Stainless Steel
Strip coating	Plasma with Silane	n.a.	Plasma with Silane
Effective Length (cm)	150	150	150
Balloon Compliance	Semi Compliant	Semi Compliant	Semi Compliant

[1] Ibid.

	Subject Device	**Predicate Device** *Serranator Alto[1] PTA Serration Balloon Catheter* **(Not Commercialized)**	**Reference Device** *Serranator PTA Serration Balloon Catheter* **(Commercialized)**
Balloon top layer	Pre-Fabricated Cover (PFC)	Urethane (dip coat)	Pre-Fabricated Cover (PFC)
Balloon base layer	Urethane	Urethane	Urethane
Balloon base	Nylon	Nylon	Nylon
Sterilization Method	Ethylene Oxide Gas	Ethylene Oxide Gas	Ethylene Oxide Gas
Nominal Pressure (atm)	6	6	6
Hydrophilic Coating	No	Yes	No
Rated Burst Pressure (atm)	10	12	12
Packaging	Tyvek® Pouch and Carton Packaging Hoop/Hoop Attachment	Tyvek® Pouch and Carton Packaging Hoop/Hoop Attachment	Tyvek® Pouch and Carton Packaging Hoop/Hoop Attachment

NON-CLINICAL TESTING/PERFORMANCE DATA:

The following bench tests were performed based on a risk assessment of the subject device and its alignment with the cleared predicate (K163380) and the reference device (K203437) catheter design, materials, and processes.

Non-clinical bench testing was performed on the subject device to determine substantial equivalence. The following tests were performed:

- Catheter Delivery, Deployment and Retraction
- Balloon Rated Burst Test
- Balloon Fatigue
- Catheter Torsion
- Catheter Flex/Kink
- Catheter Tensile Test

In vitro bench testing demonstrated that the subject device performed as intended and similar to the predicate device.

BIOCOMPATIBILITY:

Biocompatibility testing was not repeated for the subject device as there were no new materials or manufacturing process changes as compared to the identical fabrication methods of the previously cleared reference device K203437.

SHELF LIFE:

Shelf life testing was not repeated for the subject device as there were no new materials or manufacturing process changes as compared to the identical fabrication methods of the previously cleared reference device K203437. The testing for the subject device of K203437 indicated that there were no differences in performance of unaged and aged devices.

CONCLUSION:

The Serranator® PTA Serration Balloon Catheter included in this notification is substantially equivalent to the previously cleared predicate device in terms of intended use and technological characteristics as demonstrated by bench testing.