May 4, 2022

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

Re: K220704
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 8, 2022
Received: March 10, 2022

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. 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,

For
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)*
K220704

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, popliteal, infrapopliteal 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.

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."

Cagent Vascular, Inc.
150 Strafford Avenue #315
Wayne, PA 19087

510(k) Summary

Serranator® PTA Serration Balloon Catheter
Cagent Vascular, Inc.

K220704

DATE PREPARED	May 4, 2022
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 Fax: (610) 688-2667 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 DEVICE	Predicate Device: *Serranator*® PTA Serration Balloon Catheter (K213728) Reference Device: *Serranator*® PTA Serration Balloon Catheter (K203437)

5.1 Intended Use/Indications for Use

The *Serranator*® PTA Serration Balloon Catheter is intended for dilatation of lesions in the iliac, femoral, iliofemoral, popliteal, infrapopliteal arteries and for the treatment of obstructive

lesions of native or synthetic arteriovenous dialysis fistulae. 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 multiple 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.

This 510(k) Summary represents a consolidation (i.e., bundling) of previously cleared 510(k) indication statements and labeling. Bundled devices are identical to previously cleared devices, the predicate device Serranator® PTA Serration Balloon Catheter (K213728) and reference device Serranator® PTA Serration Balloon Catheter (K203437). The bundled device sizes are shown in Table 5.1.

Table 5.1

	Balloon Nominal OD [mm]	**Balloon Length [mm]**			
		40	**80**	**120**	
Subject Device Serranator® PTA Serration Balloon Catheter	2.5	✓	✓	✓	**Reference Device** Serranator® PTA Serration Balloon Catheter (K203437)
	3.0	✓	✓	✓	
	3.5	✓	✓	✓	
	4.0	✓	N.A.*	✓	**Predicate** Device Serranator® PTA Serration Balloon Catheter (K213728)
	5.0	✓		✓	
	6.0	✓		✓	

*The 80mm length size is commercially available for the below the knee sizes only.

5.3 Comparison to Predicate and Reference Devices

A comparison of the *Serranator*® PTA Serration Balloon Catheter (*Serranator*) to the predicate device shows that the technological characteristics such as the components, design, materials,

sterilization method, and operating principle of the *Serranator* are identical to the currently marketed *Serranator*® PTA Serration Balloon Catheter (*Serranator*) (K213728) and the *Serranator*® PTA Serration Balloon Catheter (*Serranator*) (K203437).

The intended use of the subject device is identical to the combination of the predicate device, *Serranator*® PTA Serration Balloon Catheter (K213728) and the *Serranator*® PTA Serration Balloon Catheter (*Serranator*) (K203437), as shown in Table 5.2.

Table 5.2
Indications for Use statements of the Subject and Predicate Device

	Device Name	Indications For Use
Subject Device	*Serranator*® PTA Serration Balloon Catheter	The *Serranator*® PTA Serration Balloon Catheter is intended for dilatation of lesions in the iliac, femoral, iliofemoral, popliteal, infrapopliteal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. Not for use in the coronary or neuro-vasculature.
Predicate Device	*Serranator*® PTA Serration Balloon Catheter (K213728)	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.
Reference Device	*Serranator*® PTA Serration Balloon Catheter (K203437)	The Serranator® PTA Serration Balloon Catheter is intended for dilatation of lesions in infrapopliteal arteries. Not for use in the coronary or neuro-vasculature.

5.4 Previous Non-Clinical and Pre-Clinical Testing

The devices represented herein are identical to the predicate and reference devices (Serranator® PTA Serration Balloon Catheter (Serranator) (K213728) and the Serranator® PTA Serration Balloon Catheter (Serranator) (K203437)). All non-clinical and pre-clinical testing has been leveraged from those submissions.

5.5 Conclusion

No new data are included in this bundled 510(K) application. The *Serranator*® PTA Serration Balloon Catheters represented in this bundled submission do not differ in purpose, design, materials, energy source, function, or any other feature. Performance data previously provided in K213728 and K203437 demonstrate that the devices function as intended.