April 2, 2026

Verge Medical, Inc.
% Reynier Jacinto
Principal Regulatory Consultant
Bridge City Regulatory, LLC
5331 S Macadam Ave.
Suite 258, Pmb #708
Portland, Oregon 97239

Re: K254022
Trade/Device Name: FLASH Flex™ Aorto-Ostial Angioplasty System
Regulation Number: 21 CFR 870.5100
Regulation Name: Percutaneous Transluminal Coronary Angioplasty (Ptca) Catheter
Regulatory Class: Class II
Product Code: LOX
Dated: February 27, 2026
Received: March 2, 2026

Dear Reynier Jacinto:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Jenny R. Katsnelson -S

Digitally signed by Jenny R. Katsnelson -S
Date: 2026.04.02 08:59:22 -04'00'

for Lydia Glaw
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)*
K254022

Device Name
Flash Flex Aorto-Ostial Angioplasty System

Indications for Use *(Describe)*
Flash Flex Aorto-Ostial Angioplasty system is indicated for the post delivery expansion of balloon expandable stents within the coronary 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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510(k) Summary
[per 21 CFR 807.87(h) and 21 CFR 807.92]

747 Camden Avenue, Suite A, Campbell, CA 95008 USA

FLASH Flex™ Aorto-Ostial Angioplasty System

510(k):	K254022
Date Prepared:	15 DEC 2025
Submitter:	Verge™ Medical, Inc. 747 Camden Avenue, Suite A Campbell, CA 95008, USA
Contact:	Jon Bohane, GM and COO Tel: 844-352-7411
Device Name:	FLASH Flex™ Aorto-Ostial Angioplasty System
Predicate Device:	FLASH™ Mini Ostial System
Device Classification:	Class II per 21 CFR §870.5100
Classification Name:	Catheters, Transluminal Coronary Angioplasty, Percutaneous
Product Code	LOX

Intended Use / Indications for Use:
The FLASH Flex™ Aorto-Ostial Angioplasty System is indicated for the post-delivery expansion of balloon expandable stents within the coronary vasculature.

Device Description:
The FLASH Flex™ Aorto-Ostial Angioplasty System (FLASH Flex™ System) is a family of rapid exchange (RX) dual balloon catheter systems that are available in multiple balloon diameter and length configurations. The catheters include a pressure relief feature that reduces the potential for over-pressurization of the Proximal Balloon. They are compatible with 0.014" (0.36 mm) guidewires and 6 Fr guide catheters. The FLASH Flex™ System includes a 20cc locking syringe for balloon inflation and deflation.

Comparison with predicate device:
The FLASH Flex™ is an update to the currently cleared coronary FLASH catheters that implements design changes to improve certain aspects of the device. It is similar in design and identical in principle of operation to its predicate device, the FLASH™ Mini Ostial System. The differences in design between the subject and the predicate devices were made to enhance tip flexibility, catheter trackability, addition of Fluorosaver™ markers to reduce fluoro/radiation exposure, simplify the device's preparation, and validate the use of ethylene oxide sterilization. Additionally, Verge™ Medical, Inc is seeking to narrow the indications for use of the subject device to solely focus use on, "post-delivery expansion of balloon expandable stents within the coronary vasculature."

Description	Subject Device	Predicate Device
Device Name	FLASH Flex™ Aorto-Ostial Angioplasty System	FLASH™ Mini Ostial System
Manufacturer	Verge™ Medical, Inc.	Verge™ Medical, Inc. (formerly Ostial Corporation)
510(k) #	K254022	K152485
Intended Use	Percutaneous Transluminal Coronary Angioplasty	Same
Indications for Use	The FLASH Flex™ Aorto-Ostial Angioplasty System is indicated for the post-delivery expansion of balloon expandable stents within the coronary vasculature.	The FLASH™ Mini Ostial System is indicated for balloon dilatation of the stenotic portion of a coronary artery or bypass graft for the purpose of improving myocardial perfusion. The FLASH™ Mini Ostial System is also indicated for the post-delivery expansion of balloon expandable stents within the coronary vasculature.

Product Code	LOX	Same
Regulation Name/Number	Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter; 21 CFR 870.5100	Same
Class	II	Same
Prescription/ Over-the-Counter	Prescription Only	Same
Single Use Only?	Yes	Same
Provided Sterile?	Yes	Same
Sterilization Method	Ethylene Oxide (EO)	E-beam
Packaged Components	Dual Balloon Catheter 20cc Syringe	Dual Balloon Catheter 10cc Syringe 1cc Syringe
Guidewire Compatibility	0.014" (0.36 mm)	Same
Guide Catheter Compatibility	6 Fr	Same
Catheter Sizes (balloon dia. x balloon length x working length)	3.0mm x 8mm x 135cm 3.5mm x 8mm x 135cm 4.0mm x 8mm x 135cm 4.5mm x 8mm x 135cm 5.0mm x 12mm x 135cm	3.0mm x 8mm x 135cm 3.5mm x 8mm x 135cm 4.0mm x 8mm x 135cm 4.5mm x 8mm x 135cm
Nominal Pressures	3.0mm: 9 ATM 3.5mm: 9 ATM 4.0mm: 9 ATM 4.5mm: 9 ATM 5.0mm: 8 ATM	3.0mm: 9 ATM 3.5mm: 9 ATM 4.0mm: 9 ATM 4.5mm: 9 ATM
Rated Balloon Pressures	3.0mm: 16 ATM 3.5mm: 16 ATM 4.0mm: 16 ATM 4.5mm: 16 ATM 5.0mm: 12 ATM	3.0mm: 20 ATM 3.5mm: 20 ATM 4.0mm: 20 ATM 4.5mm: 20 ATM
Materials	Medical-grade Nylon plastics, Pt/Ir, Stainless Steel, Polycarbonate, Silicone and Cyanoacrylate	Similar

Non-Clinical testing / Performance Data:

Non-clinical laboratory testing was performed on the FLASH Flex™ System to assure compliance with all pre-specified, clinically relevant acceptance criteria and to demonstrate substantial equivalence to the predicate device as it relates to their intended use. The following testing/assessments were performed:

- Visual and Dimensional Testing
- Tensile / Bond Strength Testing
- Torque Testing
- Burst Pressure Testing
- Balloon Fatigue Testing
- Drop Testing
- Package Testing
- Fluid Leak Testing
- Simulated Use Performance Testing

The performance bench tests demonstrated that the FLASH Flex™ System met all pre-defined acceptance criteria demonstrating that the subject device functions as intended and is substantially equivalent to the predicate device.

Biocompatibility:
Testing was performed to assess biocompatibility of the FLASH Flex™ System's patient-contacting components. The following tests were successfully performed:

- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity
- Acute Systemic Toxicity
- Material Mediated Pyrogenicity
- Hemocompatibility
  - o Hemolysis (Direct)
  - o Thrombosis (PTT Assay)
  - o Thrombosis (SC5b-9 Elisa Assay)
  - o Thrombosis (Platelet and Leukocyte Measurement)

Adherence to the test methodologies and standards was maintained in all biocompatibility testing described. Each of the biocompatibility tests defined above passed pre-defined acceptance

criteria. There was no evidence of toxicity, sensitization, or irritation. Testing found samples to be non-hemolytic, non-activator, and non-pyrogenic. All testing was conducted in compliance with GLP regulations, 21 CFR Part 58.

In-Vivo GLP Pre-Clinical Testing / Performance Data:
No animal studies were required to demonstrate substantial equivalence between the subject and predicate devices.

Conclusion:
The Verge ™ Medical, Inc. FLASH Flex™ System has similar intended use and the same or similar technological characteristics in its design, materials, and operating principles as the predicate device. Performance data demonstrates that the device functions as intended. The non-clinical performance tests demonstrate that the FLASH Flex™ System is substantially equivalent to the predicate device.