June 11, 2026

Instylla, Inc.
Easwar Prabakaran
Regulatory Specialist II
201 Burlington Rd.
North Bldg.
Bedford, Massachusetts 01730

Re: K261610
Trade/Device Name: Verge™ Microcatheter
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous flush catheter
Regulatory Class: Class II
Product Code: KRA
Dated: May 14, 2026
Received: May 14, 2026

Dear Easwar Prabakaran:

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,

GREGORY W. O'CONNELL -S

Digitally signed by GREGORY W. O'CONNELL -S
Date: 2026.06.11 12:59:26 -04'00'

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K261610

Device Name
Verge™ Microcatheter

Indications for Use *(Describe)*
The Verge™ Microcatheter is intended for use in small vessel or subselective anatomy for peripheral vascular diagnostic and interventional procedures. The Verge™ Microcatheter can be used for the infusion of diagnostic, embolic, or therapeutic materials into vessels.

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

Submitter Information:

Instylla, Inc.
201 Burlington Rd
North Building
Bedford, MA 01730

Contact Person:

Easwar Prabakaran
Regulatory Specialist II
Phone: 813-471-7585
E-mail: easwarp@instylla.com

Date Prepared:

June 11, 2026

Subject Device:

Proprietary Name:	Verge™ Microcatheter
Common Name:	Catheter, Continuous Flush
Classification Name:	Continuous Flush Catheter
Classification Regulation:	21 CFR 870.1210
Product Code:	KRA
Device Classification:	Class II
Classification Panel:	Cardiovascular

Primary Predicate Device:

Proprietary Name:	Instylla 1.2 Microcatheter
Manufacturer:	Instylla, Inc.
510(k) Number:	K210808

Secondary Predicate Device:

Proprietary Name:	Instylla Microcatheter
Manufacturer:	Instylla, Inc.
510(k) Number:	K200744

Device Description:

The Verge™ Microcatheter device is a single lumen, multipurpose catheter intended for use in the peripheral vasculature. The basic operating principle is to advance the microcatheter through a guiding

catheter and track coaxially over a steerable guidewire to access the treatment site. The microcatheter lumen can accommodate steerable guidewires that are ≤ 0.014" (0.36 mm) in diameter for the 1.7 Fr size and ≤ 0.010" (0.25 mm) for the 1.2 Fr size. Once the target region has been accessed, the microcatheter can be used to deliver diagnostic, embolic, or therapeutic materials into vessels.

The Verge™ Microcatheter has a 1.2 Fr (0.40 mm) or 1.7 Fr (0.56 mm) outside diameter (OD) with constant flexibility along its length. The inner diameter (ID) of the microcatheter is 0.012" (0.30 mm) or 0.016" (0.41 mm) along its length. The proximal end of the microcatheter incorporates a standard luer hub to enable the attachment of accessories and a strain relief that allows for flexibility and securement inside a Tuohy-Borst adapter for maintaining position inside a guiding catheter as needed. The Verge™ Microcatheter has a radiopaque marker at the distal tip to aid in fluoroscopic visualization. A 4Fr Tuohy-Borst with a side-port adapter, a short catheter extension, a long catheter extension adapter, and a duckbill check valve are also included. The Verge™ Microcatheter System is available in 122 cm, 142 cm, and 162 cm usable lengths.

Indications for Use:
The Verge™ Microcatheter is intended for use in small vessel or sub selective anatomy for peripheral vascular diagnostic and interventional procedures. The Verge™ Microcatheter can be used for the infusion of diagnostic, embolic, or therapeutic materials into vessels.

Comparison of Technological Characteristics to the Predicate Device:
The Verge™ Microcatheter is substantially equivalent in intended use and fundamental technological characteristics to the legally marketed predicate devices. The below table summarizes the similarities in design and configuration of the Verge™ Microcatheter compared with the predicate devices.

Attribute	Subject Device: Verge™ Microcatheter	Primary Predicate Device: Instylla 1.2 Microcatheter (K210808)	Secondary Predicate Device: Instylla Microcatheter (K200744)	Substantial Equivalence
Indications for Use	The Verge™ Microcatheter is intended for use in small vessel or sub selective anatomy for peripheral vascular diagnostic and interventional procedures. The Verge™ Microcatheter	The Instylla Microcatheter 1.2 is intended for use in small vessel or super selective anatomy for peripheral diagnostic and interventional procedures. The Instylla	The Instylla Microcatheter is intended for use in small vessel or super selective anatomy for peripheral diagnostic and interventional procedures. The Instylla Microcatheter can be used for	Similar

Attribute	Subject Device: Verge™ Microcatheter	Primary Predicate Device: Instylla 1.2 Microcatheter (K210808)	Secondary Predicate Device: Instylla Microcatheter (K200744)	Substantial Equivalence
	can be used for the infusion of diagnostic, embolic, or therapeutic materials into vessels.	Microcatheter 1.2 can be used for the infusion of diagnostic, embolic, or therapeutic materials into vessels.	the infusion of diagnostic, embolic, or therapeutic materials into vessels.	
Basic Design/ Components	Microcatheter, 4Fr Tuohy Borst with Side Port-Adaptor, Short Extension Adapter, Long Extension Adapter and Duckbill Check-Valve Connector	Microcatheter, 4Fr Tuohy Borst with Side Port-Adaptor, Short Extension Adapter, Long Extension Adapter and Duckbill Check-Valve Connector	Microcatheter, 4Fr Tuohy Borst with Side Port-Adaptor, Short Extension Adapter, Long Extension Adapter and Duckbill Check-Valve Connector	Same
Microcatheter Materials	Hub – Polycarbonate Shaft –PEBAX 72D/63D, Stainless Steel, PTFE, Platinum/Iridium Marker Band Distal Tip– PEBAX 63D	Hub – Polycarbonate Shaft –PEBAX 72D/63D, Stainless Steel, PTFE, Platinum/Iridium Marker Band Distal Tip– PEBAX 72D/40D	Hub – Polycarbonate Shaft –PEBAX 72D/63D, Stainless Steel, PTFE, Platinum/Iridium Marker Band Distal Tip– PEBAX 72D/40D	The subject and predicate device's materials remain the same with the exception of the distal tip material which was modified to improve the Microcatheter manufacturability.
Principle of Operation	Manually tracked over a steerable guidewire to access vasculature.	Manually tracked over a steerable guidewire to access vasculature.	Manually tracked over a steerable guidewire to access vasculature.	Same

Attribute	Subject Device: Verge™ Microcatheter	Primary Predicate Device: Instylla 1.2 Microcatheter (K210808)	Secondary Predicate Device: Instylla Microcatheter (K200744)	Substantial Equivalence
Contraindications	The Verge™ Microcatheter is not intended to be used in coronary or neurovasculature. The safety and effectiveness of the Verge™ Microcatheter in pediatric patients has not been established.	The Verge™ Microcatheter is not intended to be used in coronary or neurovasculature.	The Verge™ Microcatheter is not intended to be used in coronary or neurovasculature.	The subject device includes a pediatric contraindication.
Inner Diameter (ID)	1.7 Fr: 0.016 in (0.41 mm) 1.2 Fr: 0.012 in (0.30 mm)	0.012 in (0.30 mm)	0.016 in (0.41 mm)	Same
Catheter Shaft Outer Diameter (OD)	1.7 Fr (0.56 mm) 1.2 Fr (0.40 mm)	1.2 Fr (0.40 mm)	1.7 Fr (0.56 mm)	Same
Catheter Lengths	122 cm, 142 cm, 162 cm	122 cm, 142 cm, 162 cm	122 cm, 142 cm, 162 cm	Same
Guidewire Compatibility (Size)	1.7 Fr: 0.014 in (0.36 mm) 1.2 Fr: 0.010 in (0.25 mm)	0.010 in (0.25 mm)	0.014 in (0.36 mm)	Same
Radiopaque Marker	Yes	Yes	Yes	Same
Packaging	Tyvek Pouches	Tyvek Pouches	Tyvek Pouches	Same
Sterilization Method	Ethylene Oxide (EO) to a SAL of 10^{-6}	Ethylene Oxide (EO) to a SAL of 10^{-6}	Ethylene Oxide (EO) to a SAL of 10^{-6}	Same
Shelf Life	6 months	6 months	6 months	Same
Hub Proximal End – Transition	Smooth transition from the hub into	Small “step” in the hub. Tapers	Small “step” in the hub. Taper	The more gradual internal transition

Attribute	Subject Device: Verge™ Microcatheter	Primary Predicate Device: Instylla 1.2 Microcatheter (K210808)	Secondary Predicate Device: Instylla Microcatheter (K200744)	Substantial Equivalence
from Hub to Microcatheter Lumen	the catheter lumen	down to the ID of the lumen.	down to the ID of the lumen.	from hub to catheter shaft ID improves guidewire insertion

The subject and primary predicate device differ from one another in the packaging, labeling, distal tip material, and design of hub to microcatheter transition.

The indications for use, principle of operations, and technological characteristics are similar between the subject and predicate devices.

Performance Data

Performance testing of the sterilized Verge™ Microcatheter included bench testing and functional testing to verify specifications fundamental to the design of the device in accordance with the FDA Guidance for Industry *Peripheral Percutaneous Transluminal Angioplasty (PTA) and Specialty Catheters – Premarket Notification (510(k)) Submissions* and ISO 10555-1 *Intravascular catheters – Sterile and single-use catheters – Part 1: General Requirements*. Testing included the following:

- Visual Inspection of Components
- Dimensional Verification of Components
- Trackability
- Kink Resistant
- Pushability
- Tip Stability
- Injection of Fluids
- Static Burst Pressure
- Freedom from Leakage – Fluids
- Freedom from Leakage – Air
- Catheter Tensile Strength
- Microcatheter Compatibility with Microcatheters, Embolic Agents
- Accessory Compatibility and Functionality
- Torque Strength

The Verge™ Microcatheter met the predetermined acceptance criteria ensuring substantial equivalence to the predicate device. No new safety or performance issues were raised during testing.

Biocompatibility Testing

A biocompatibility evaluation was conducted in accordance with the FDA Guidance for Industry, *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process,"* consistent with an external communicating circulating blood

device with limited body contact. The following biocompatibility tests were successfully completed on the Verge™ Microcatheter:

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Material Mediated Pyrogenicity
- Hemolysis
- Complement Activation Assay
- Partial Thromboplastin Time Assay
- *In Vivo* Thromboresistance Study

Sterility

The Verge™ Microcatheter is sterilized via an Ethylene Oxide (EO) process to a Sterility Assurance Level (SAL) of 10^{-6}. The sterilization process was validated per ISO 11135 *Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices.* The Verge™ Microcatheter was evaluated and adopted into the validated process per AAMI TIR28 *Product adoption and process equivalence for ethylene oxide sterilization*. The EO and ECH levels were determined to be acceptable in accordance with ISO 10993-7 *Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals*.

A bacterial endotoxin test (BET), also known as the Limulus amebocyte lysate (LAL) test, was also validated to establish that the Verge™ Microcatheter endotoxin level will be <20 endotoxin units (EU)/device.

Packaging

Packaging testing was conducted on sterilized Verge™ Microcatheter to evaluate the effectiveness of the packaging configuration to maintain the sterile barrier in accordance with ISO 11607-1 *Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems*. The subject device and packaging were subjected to simulated distribution challenge conditions in accordance with International Safe Transit Association (ISTA) 3A and evaluated for performance of the sterile barrier and product performance.

Shelf Life

The Verge™ Microcatheter has a 6 month shelf life. Shelf life studies have been conducted to demonstrate that the device maintains its performance and the packaging will maintain its sterile barrier over the entirety of the intended shelf life.

Conclusion

Instylla has demonstrated that the Verge™ Microcatheter is substantially equivalent in fundamental design, function, device materials, packaging, sterilization, operating principle, intended use/indication for use and fundamental technology as the legally marketed predicate devices, the Instylla 1.2 Microcatheter

which was cleared under 510(k) Premarket Notification K210808 on April 15, 2021, and the Instylla Microcatheter which was cleared under 510(k) Premarket Notification K200744 on April 21, 2020.