April 15, 2021

Instylla, Inc.
Jennifer Greer
Regulatory Affairs Manager
201 Burlington Road,
North Building
Bedford, Massachusetts 01730

Re: K210808
Trade/Device Name: Instylla Microcatheter 1.2
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II
Product Code: KRA
Dated: March 16, 2021
Received: March 17, 2021

Dear Jennifer Greer:

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 W. O'connell -S

Digitally signed by Gregory W. O'connell -S
Date: 2021.04.15 11:45:22 -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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K210808

Device Name
Instylla Microcatheter 1.2

Indications for Use *(Describe)*
The Instylla Microcatheter 1.2 is intended for use in small vessel or super selective anatomy for peripheral diagnostic and interventional procedures. The Instylla Microcatheter 1.2 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.***

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**510(k) Summary - K210808**

**Submitter Information:**

Instylla, Inc.
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Bedford, MA 01730

**Contact Person:**

Jennifer Greer
Regulatory Affairs Manager
Phone: 781-622-9293
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**Date Prepared:**

March 16, 2021

**Subject Device:**

| | |
|---|---|
| Proprietary Name: | Instylla Microcatheter 1.2 |
| Common Name: | Catheter, Continuous Flush |
| Classification Name: | Continuous flush catheter (21 CFR 870.1210, Product Code KRA) |
| Device Classification: | Class II |
| Classification Panel: | Cardiovascular |

**Predicate Devices:**

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

**Device Description:**

The Instylla Microcatheter 1.2 includes a single lumen, multipurpose catheter intended for use in the peripheral vasculature. The basic operating principle is to advance the microcatheter through an outer guiding catheter and track coaxially over a steerable guidewire in order to access the treatment site. The microcatheter lumen is able to accommodate steerable guidewires that are ≤0.010in (0.25mm) in diameter. Once the target region has been accessed, the microcatheter can be used to deliver diagnostic, embolic, or therapeutic materials into vessels.

The microcatheter has a 1.2Fr (0.40mm) OD with a constant flexibility along its length. The ID of the microcatheter is 0.012in (0.30mm) along its length. The proximal end of the microcatheter incorporates

a standard luer hub to enable the attachment of accessories, and a strain relief with a feature that allows for flexibility and securement inside a Tuohy-Borst with side-port adapter, for maintaining position inside a guiding catheter as needed. The microcatheter has a radiopaque marker at the distal tip to aid in fluoroscopic visualization. A 4Fr Tuohy-Borst with side-port adapter, a short extension adaptor, a long extension adapter and a duckbill check-valve are also included. The Instylla Microcatheter is available in 122cm, 142cm and 162cm usable lengths.

**Indications for Use:**
The Instylla Microcatheter 1.2 is intended for use in small vessel or super selective anatomy for peripheral diagnostic and interventional procedures. The Instylla Microcatheter 1.2 can be used for the infusion of diagnostic, embolic, or therapeutic materials into vessels.

The indications for use statement for the modified Instylla Microcatheter 1.2 remains unchanged from the cleared predicate device.

**Comparison of Technological Characteristics to the Predicate Devices:**
The Instylla Microcatheter 1.2 is substantially equivalent in intended use and fundamental technological characteristics to the legally marketed predicate device. The below table summarizes the similarities in design and configuration of the Instylla Microcatheter 1.2 compared with the predicate device.

| **Attribute** | **Subject Device: Instylla Microcatheter 1.2** | **Predicate Device: Instylla Microcatheter (K200744)** | **Substantial Equivalence** |
|---|---|---|---|
| Indications for Use | 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 the infusion of diagnostic, embolic, or therapeutic materials into vessels. | 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 the infusion of diagnostic, embolic, or therapeutic materials into vessels. | Same |
| Basic Design/ Components | Microcatheter, 4Fr Tuohy-Borst with Side Port Adaptor, Short Extension Adapter, Long Catheter Adapter and Duckbill Check-Valve Connector | Microcatheter, 4Fr Tuohy-Borst with Side Port Adaptor, Short Extension Adapter, Long Catheter Adapter and Duckbill Check-Valve Connector | Same |
| Catheter Material | Thermoplastic elastomers (PEBAX), PTFE (inner layer), platinum/iridium marker, polycarbonate (hub) | Thermoplastic elastomers (PEBAX), PTFE (inner layer), platinum/iridium marker, polycarbonate (hub) | Same |
| Principle of Operation | Manually tracked over a steerable guidewire to access vasculature. | Manually tracked over a steerable guidewire to access vasculature. | Same |
| Inner Diameter | 0.012 in (0.30mm) | 0.016in (0.41mm) | The subject device has a |

| Attribute | Subject Device: Instylla Microcatheter 1.2 | Predicate Device: Instylla Microcatheter (K200744) | Substantial Equivalence |
|---|---|---|---|
| | | | smaller inner diameter. |
| Outer Diameter | 1.2Fr (0.40mm) | 1.7Fr (0.56mm) | The subject device has a smaller outer diameter. |
| Usable Lengths | 122cm, 142cm, 162cm | 122cm, 142cm, 162cm | Same |
| Guidewire Compatibility (Size) | 0.010in (0.25mm) | 0.014in (0.36mm) | The change in outer diameter results in compatibility with a smaller guidewire. |
| Radiopaque Marker | Yes | Yes | Same |
| Method of Sterilization | 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 | Same |

The modified Instylla Microcatheter 1.2 only differs from the legally marketed predicate device in that it has a 1.2Fr OD compared to the 1.7Fr OD of the predicate device. The intended use, indications, principle of operation, packaging, sterilization and technological characteristics remain identical between the subject and predicate device.

**Performance Data**

Performance testing of the final, sterilized Instylla Microcatheter 1.2 included bench testing and functional testing to verify specifications related to the modification of the device. The following testing was repeated for the modified device:

- Visual Inspection of Components
- Dimensional Verification of Components
- Trackability
- Kink Resistance
- Pushability and Torqueability
- Tip Radiopacity
- Fluid and Infusate Compatibility
- Injection of Fluids (Flowrate) and Tip Stability
- Freedom from Leakage
- Static Burst Pressure

- Catheter Shaft Tensile Strength
- Microcatheter Compatibility with Standard Microcatheters, Guidewires and Syringes
- Accessory Compatibility and Functionality

The Instylla Microcatheter 1.2 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 on the Instylla Microcatheter 1.2 in accordance with the FDA Guidance Document *Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process."* The following biocompatibility tests were successfully completed to demonstrate substantial equivalence of the modified Instylla Microcatheter 1.2:

- Cytotoxicity
- Sensitization
- Irritation or Intracutaneous Toxicity
- Acute Systemic Toxicity
- Material-Mediated Pyrogenicity
- Hemolysis
- Complement Activation
- Partial Thromboplastin Time
- In Vivo Thromboresistance – Jugular Vein

**Sterility**
The Instylla Microcatheter 1.2 is sterilized via a validated 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 Instylla Microcatheter 1.2 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 microcatheter endotoxin level will be <20 endotoxin units (EU)/device.

**Shelf Life**
The Instylla Microcatheter 1.2 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.

**Clinical Performance Data**
The fundamental technological characteristics, indications for use, material, manufacturing and sterilization processes are the same as the predicate devices and therefore, no clinical studies were deemed necessary to demonstrate the safety and effectiveness of the subject device.

**Conclusion**

Instylla has demonstrated that the Instylla Microcatheter 1.2 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 device, Instylla Microcatheter, which was cleared under 510(k) Premarket Notification K200744 on April 21, 2020.