August 13, 2019

Instylla, Inc.
Ms. Amita Shah
Vice President, Regulatory and Quality Affairs
204 Second Avenue
Waltham, MA 02451

Re: K191731
   Trade/Device Name: Instylla Microcatheter
   Regulation Number: 21 CFR 870.1210
   Regulation Name: Continuous Flush Catheter
   Regulatory Class: Class II
   Product Code: KRA
   Dated: June 27, 2019
   Received: June 28, 2019

Dear Ms. Shah:

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](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.


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
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
Indications for Use

510(k) Number (if known)
K191731

Device Name
Instylla Microcatheter

Indications for Use (Describe)
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.

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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"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."
Submitter Information:
Instylla, Inc.
204 2nd Avenue
Waltham, MA 02451

Contact Person:
Amita Shah
VP Regulatory and Quality Affairs
Phone: 781-790-4857
Email: amitas@instylla.com

Date Prepared:
August 8, 2019

Subject Device:
Proprietary Name: Instylla Microcatheter
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: CrossCath Support Catheter
Manufacturer: Cook Incorporated
510(k) Number: K093052

The Renegade™ HI-FLO™ Microcatheter cleared under 510(k) Premarket Notification K140329 was used as a reference device in this submission.

Device Description:
The Instylla 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 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 ≤ 0.014 in (0.36 mm) in diameter. Once the target region has been accessed, the microcatheter can be used to deliver diagnostic, embolic, or therapeutic materials into vessels.

The Instylla Microcatheter has a 1.7Fr (0.56mm) OD with a constant flexibility along its length. The ID of the microcatheter is 0.016 in (0.41mm) 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 allow for flexibility and securement inside a Tuohy-Borst adapter, for maintaining position inside a guiding catheter as needed. The Instylla Microcatheter has a radiopaque marker at the distal tip to aid in fluoroscopic visualization. A 4Fr Tuohy-Borst with side-port adapter, a short catheter extension and a long catheter extension adapter are also included. The Instylla Microcatheter is available in 122, 142 and 162 cm usable lengths.

**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 indications for use statement is similar to the predicate device, CrossCath Support Catheter.

**Comparison of Technological Characteristics to the Predicate Devices:**
The Instylla 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 Instylla Microcatheter compared with the predicate devices.

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Subject Device: Instylla Microcatheter</th>
<th>Predicate Device: CrossCath Support Catheter (K093052)</th>
<th>Reference Device: Renegade HI-FLO Microcatheter (K140329)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indications for Use</td>
<td>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.</td>
<td>The CrossCath Support Catheter is intended for use in small vessel or super selective anatomy for diagnostic and interventional procedures, including peripheral use.</td>
<td>The Renegade HI-FLO Microcatheter is intended for peripheral vascular use. The microcatheter can be coaxially tracked over a steerable guidewire in order to access distal, tortuous vasculature. Once the subselective region has been accessed, the microcatheter can be used for the controlled and selective infusion of</td>
</tr>
<tr>
<td>Attribute</td>
<td>Subject Device: Instylla Microcatheter</td>
<td>Predicate Device: CrossCath Support Catheter (K093052)</td>
<td>Reference Device: Renegade HI-FLO Microcatheter (K140329)</td>
</tr>
<tr>
<td>--------------------------</td>
<td>--------------------------------------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------</td>
<td>-----------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td></td>
<td>Instylla Microcatheter 4Fr Tuohy Borst with Side Port Adaptor, Short Extension Adapter, and Long Extension Adapter</td>
<td>Microcatheter</td>
<td>Renegade HI-FLO Microcatheter, Rotating hemostatic valve, Shaping mandrel</td>
</tr>
<tr>
<td>Basic Design/ Components</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Material</td>
<td>Thermoplastic elastomers (PEBAX), PTFE (inner layer), platinum/iridium marker, polycarbonate (hub)</td>
<td>Catheter material not known, platinum/iridium marker</td>
<td>Fiber Palladium Braid</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Outer surface coated with Hydro Pass™ Hydrophilic Coating, platinum-tungsten tip</td>
</tr>
<tr>
<td>Principle of Operation</td>
<td>Manually tracked over a steerable guidewire to access vasculature.</td>
<td>Manually tracked over a steerable guidewire to access vasculature.</td>
<td>Manually tracked over a steerable guidewire to access vasculature.</td>
</tr>
<tr>
<td>Inner Diameter</td>
<td>0.016 in (0.41mm)</td>
<td>Not known, 0.014-0.035 in guidewire compatibility dependent on catheter configuration</td>
<td>0.027 in (0.69 mm)</td>
</tr>
<tr>
<td>Outer Diameter</td>
<td>1.7 Fr (0.56mm)</td>
<td>1.9-3.7 Fr, dependent on catheter configuration</td>
<td>2.8 Fr (0.93 mm) to 3.0 Fr (1.00 mm) (tapered design)</td>
</tr>
<tr>
<td>Usable Lengths</td>
<td>122 cm, 142 cm, 162 cm</td>
<td>65cm, 90 cm, 135 cm, 150 cm</td>
<td>80 cm, 105 cm, 115 cm, 135 cm, 150 cm</td>
</tr>
<tr>
<td>Guidewire Compatibility</td>
<td>0.014 in (0.36 mm)</td>
<td>0.014 in (0.36 mm) - 0.035 in (0.89 mm)</td>
<td>0.018 in (0.47 mm)</td>
</tr>
<tr>
<td>(size)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radiopaque Marker</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>
The subject and primary predicate devices have the same intended use, similar indications, and similar technological characteristics including a similar principle of operation.

The subject and primary predicate devices differ from one another in the components that are packaged with the microcatheter, dimensions and materials. These differences do not raise any new questions about the safety and effectiveness as demonstrated by performance and biocompatibility testing and since the intended use and principal of operation are the similar between the subject and primary predicate device. Both devices are continuous flush catheters that are manually tracked over a steerable guidewire to access vasculature. Additionally, a Tuohy-Borst adapter is contained within the reference device.

**Performance Data**
Performance testing of the final, sterilized Instylla Microcatheter included bench testing and functional testing to verify specifications fundamental to the design of the device. Testing included the following:

- Visual Inspection of Components
- Dimensional Verification of Components
- Trackability
- Kink Resistance
- Pushability and Torqueability
- Tip Radiopacity
- Fluid, Infusate, and Chemical Compatibility
- Injection of Fluids (Flowrate) and Tip Stability
- Freedom from Leakage
- Static Burst Pressure
- Catheter Shaft Tensile Strength
- Microcatheter Compatibility with High Flow Microcatheters, Guidewires and Syringes
- Tuohy-Borst with Side-Port and Extension Accessory Compatibility and Functionality

Testing was also conducted to demonstrate the subject device is substantially equivalent to the predicate device. The Instylla 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 Document *Use of International Standard ISO 10993-1, “Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process,”* consistent
with a device in direct contact with circulating blood for a limited duration (≤24 hours). The following biocompatibility tests were successfully completed on the final, sterilized Instylla Microcatheter:

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

**Sterility**
The Instylla Microcatheter 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*. 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 has a shelf life of 6-months. 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, marker 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 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, CrossCath Support Catheter, which was cleared under 510(k) Premarket Notification K093052 on December 8, 2009.