January 7, 2021

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

Re: K202544
Trade/Device Name: Instylla Delivery Kit
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: December 7, 2020
Received: December 8, 2020

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,

Rumi Young, M.S., RAC.
Acting Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology 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)*
K202544

Device Name
Instylla Delivery Kit

Indications for Use *(Describe)*
The Instylla Delivery Kit is intended to be used for the intra-arterial or intra-venous administration of radiographic contrast media, saline and other aqueous solutions.

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

Submitter Information:

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

Contact Person:

Jennifer Greer
Regulatory Affairs Manager
Phone: 781-622-9293
E-mail: jennyg@instylla.com

Date Prepared:

December 7, 2020

Subject Device:

Proprietary Name:	Instylla Delivery Kit
Common Name:	Syringe, Piston
Classification Name:	Piston syringe
	(21 CFR 880.5860, Product Code FMF)
Device Classification:	Class II
Classification Panel:	General Hospital

Predicate Devices:

Proprietary Name:	Instylla Delivery Kit
Manufacturer:	Instylla, Inc.
510(k) Number:	K191659

Device Description:

The Instylla Delivery Kit is comprised of two delivery syringes, a syringe holder, and a plunger clip (link).

Indications for Use:
The Instylla Delivery Kit is intended to be used for the intra-arterial or intra-venous administration of radiographic contrast media, saline and other aqueous solutions.

The indications for use statement for the modified Instylla Delivery Kit with 3mL syringes remain unchanged from the cleared predicate device.

Comparison of Technological Characteristics to the Predicate Devices:
The Instylla Delivery Kit with 3mL syringes 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 Delivery Kit with 3mL syringes compared with the predicate devices.

Attribute	Subject Device: Instylla Delivery Kit with 3mL Syringes	Predicate Device: Instylla Delivery Kit (K191659)	Substantial Equivalence Comparison
Indications for Use	The Instylla Delivery Kit is intended to be used for the intra-arterial or intra-venous administration of radiographic contrast media, saline and other aqueous solutions.	The Instylla Delivery Kit is intended to be used for the intra-arterial or intra-venous administration of radiographic contrast media, saline and other aqueous solutions.	Same
Basic Design/ Components	Two standard delivery piston syringes	Two standard delivery piston syringes	Same
Components	Two syringes, syringe holder, plunger clip	Two syringes, syringe holder, plunger clip	Same
Material	Polycarbonate, silicone, ABS	Polycarbonate, silicone, ABS	Same
Principle of Operation	Manually operated by advancing the dual syringe plungers simultaneously with the aid of a plunger clip.	Manually operated by advancing the dual syringe plungers simultaneously with the aid of a plunger clip.	Same
Operation Volume	3mL	1mL	The operational volume of the syringes differs.

Attribute	Subject Device: Instylla Delivery Kit with 3mL Syringes	Predicate Device: Instylla Delivery Kit (K191659)	Substantial Equivalence Comparison
Gradation	Printed with accurate graduation lines that are compliant with ISO 7886-1.	Printed with accurate graduation lines that are compliant with ISO 7886-1.	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 Delivery Kit differs from the legally marketed predicate device in that it includes two 3mL syringes instead of two 1mL syringes. The intended use, indications, principle of operation, and technological characteristics remain identical between the subject and predicate device.

Performance Data

Performance testing of the final, sterilized Instylla Delivery Kit with 3mL syringes included bench testing and functional testing to verify specifications fundamental to the design of the device. The following tests were conducted:

- Visual Inspection
- Dimensional Verification
- Functional Testing
    - Syringe Holder and Plunger Clip Disconnection Force
    - Syringe Compatibility
    - Syringe Glide Force and Break Force
    - Fluids Compatibility
    - Delivery Integrity
- Particulate Matter Testing per USP <788> *Particulate Matter in Injections*

The Instylla Delivery Kit with 3mL syringes met the predetermined acceptance criteria ensuring substantial equivalence to the predicate device. No new safety or performance issues were raised during testing. Further, the syringes of the subject device are complaint against FDA recognized standards ISO 7886-1 and ISO 594-2.

Biocompatibility Testing

A biocompatibility evaluation was conducted on the Instylla Delivery Kit with 3mL syringes 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 Instylla Delivery Kit with 3mL syringes is classified as an external

communicating device, indirectly contacting blood for a limited duration (≤24 hours). The patient contact, materials and manufacturing processes remain identical between the Instylla Delivery Kit with 3mL syringes and the legally marketed predicate device. Therefore, per ISO 10993-1, the biocompatibility results of the predicate device are representative of the subject device and no additional biocompatibility testing was conducted on the subject device.

Sterility

The Instylla Delivery Kit with 3mL syringes 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 Delivery Kit with 3mL syringes 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 delivery kit endotoxin level will be <20 endotoxin units (EU)/device.

Shelf Life

The Instylla Delivery Kit with 3mL syringes 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 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 Delivery Kit with 3mL syringes is substantially equivalent in fundamental design, function, device materials, packaging, sterilization, operating principle, intended use/indication for use and technology as the legally marketed predicate device, Instylla Delivery Kit, which was cleared under 510(k) Premarket Notification K191659 on October 11, 2019.