



December 22, 2025

Instylla, Inc.  
Jennifer Greer  
Sr. Regulatory Manager  
201 Burlington Rd.  
North Bldg.  
Bedford, Massachusetts 01730

Re: K253769  
Trade/Device Name: Instylla Delivery Kit  
Regulation Number: 21 CFR 880.5860  
Regulation Name: Piston syringe  
Regulatory Class: Class II  
Product Code: FMF  
Dated: November 25, 2025  
Received: November 25, 2025

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 (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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

  
**KYRAN R. GIBSON -S**

For

Shruti Mistry

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

## Indications for Use

510(k) Number (if known)  
K253769

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.

**\*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  
[PRASStaff@fda.hhs.gov](mailto:PRASStaff@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."*



## K253769 510(k) Summary

### Submitter Information:

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

### Contact Person:

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

### Date Prepared:

December 19, 2025

### Subject Device:

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

### Predicate Device:

Proprietary Name:	Instylla Delivery Kit
Manufacturer:	Instylla, Inc.
510(k) Number:	K213632

### Device Description:

The Instylla Delivery Kit is comprised of two delivery syringes, a syringe holder, and a plunger clip (link). The barrel contains a fixed male luer connector, which is compatible with female luer hubs.

The Instylla Delivery Kit is a sterile, single patient use device intended to be used for the intra-arterial or intra-venous administration of radiographic contrast media, saline and other aqueous

solutions. The device consists of a double-barreled syringe holder which holds and couples two (2) 1mL commercially available needleless syringes with calibrated hollow barrels and movable plungers. A single plunger clip is attached to both syringe plungers to facilitate the simultaneous injection of two distinct fluids when depressed.

The syringes of the Instylla Delivery Kit are composed of polycarbonate. The plunger clip and holder are composed of Acrylonitrile Butadiene Styrene (ABS).

**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.

**Comparison of Technological Characteristics to the Predicate Device:**

The subject Instylla Delivery Kit is substantially equivalent in intended use and fundamental technological characteristics to the legally marketed predicate devices. The table below summarizes the similarities in design and configuration of the subject Instylla Delivery Kit compared with the predicate devices.

<b>Attribute</b>	<b>Subject Device: Instylla Delivery Kit</b>	<b>Predicate Device: Instylla Delivery Kit (K213632)</b>	<b>Substantial Equivalence</b>
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
Contraindications	The safety and effectiveness of the Instylla Delivery Kit in pediatric patients has not been established.	None	The subject device includes a contraindication.
Basic Design	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

Attribute	Subject Device: Instylla Delivery Kit	Predicate Device: Instylla Delivery Kit (K213632)	Substantial Equivalence
Materials	Generic Polycarbonate (PC), silicone, ABS	Polycarbonate Calibre Megarad 2081-15, silicone, ABS	The PC used in the barrel has been changed to generic PC based on the qualification of an additional source for the PC.
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
Operational Volume	1 mL	1mL or 3mL	The subject device only includes a 1mL operational volume.
Tip Type	ISO 80369-7 compliant fixed male luer connector	ISO 594-2 compliant fixed male luer connector	The syringe of the subject device is compliant with ISO 80369-7.
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
Packaging	Device is packed with a die card and placed into a tray with Tyvek lid	Device is packed with a die card and placed into a tray with Tyvek lid	Same
Sterilization Method	Ethylene Oxide (EO) to a Sterility Assurance Level (SAL) of 10 <sup>-6</sup>	EO to a SAL of 10 <sup>-6</sup>	Same
Shelf Life	6 months	6 months	Same

The subject device includes a contraindication for pediatric use. This does not impact the safety and effectiveness of subject device as the intended use is still within the scope of the predicate device. Similarly, the subject device is only offered with a syringe volume of 1mL which differs from the predicate device that is offered with a syringe volume of 1mL and 3mL. This does not impact the safety or effectiveness since the operational volume is still within the cleared volume of the predicate device.

Lastly, the supplier of the syringes has changed the material of the barrel from polycarbonate (PC), Calibre Megarad 2081-15 to generic polycarbonate. A biocompatibility evaluation was conducted by the supplier to demonstrate this change does not impact the safety or effectiveness of the Instylla Delivery Kit. The supplier of the syringes also confirmed that the syringes now conform with the requirements of ISO 80369-7. This differs from the predicate device where the barrel of each syringe contained an ISO 594-2 compliant fixed male luer connector. This does not impact the safety and effectiveness of subject device as there are no changes being made to the design or materials of the syringes.

The subject and predicate device differ from one another in packaging and labeling. The intended use, indications, principle of operation, and technological characteristics remain identical between the subject and predicate device.

#### **Performance Data**

Verification testing was conducted for product specifications related to packaging changes to the Instylla Delivery Kit. Modifications include updating the label stock suppliers for the shelf box and 2x2 label, adding patient chart peelable labels to the shelf box, and adding a heat-resistant aqueous coating to the shelf box. These changes do not impact the functional design specifications of the Instylla Delivery Kit. Therefore, only packaging validation was repeated for the Instylla Delivery Kit and no additional performance testing was performed.

The syringes of the subject device are compliant against FDA recognized standards ISO 7886-1 and ISO 80369-7.

#### **Biocompatibility Testing**

The supplier of the syringes has changed the material of the barrel from polycarbonate (PC), Calibre Megarad 2081-15 to generic polycarbonate. 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."* The Instylla Delivery Kit with modified packaging and labeling is classified as an external communicating device, indirectly contacting blood for a limited duration ( $\leq 24$  hours). Biocompatibility testing on the updated syringes was performed per the FDA Guidance. The results of the testing concluded that the updated barrel material supplier does not raise any additional biocompatibility concerns.

## **Sterility**

The Instylla Delivery Kit with modified packaging and labeling 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 modified packaging and labeling 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*.

Since the manufacturing process and materials of the Instylla Delivery Kit with modified packaging and labeling did not change, bacterial endotoxin test (BET) validation, also known as the Limulus amoebocyte lysate (LAL) test, was not repeated for the subject device.

## **Packaging**

Packaging testing was conducted on sterilized Instylla Delivery Kit with modified packaging and labeling 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 updated packaging were evaluated after accelerated aging to demonstrate that the packaging maintains the sterile barrier and package integrity over the shelf life.

## **Shelf Life**

The Instylla Delivery Kit with modified packaging and labeling 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.

## **Conclusion**

Instylla has demonstrated that the Instylla Delivery Kit is substantially equivalent in fundamental design, function, device materials, packaging, sterilization, operating principle, intended use/ indication for use and fundamental technology to the legally marketed predicate device, Instylla Delivery Kit, which was cleared under 510(k) Premarket Notification K213632 on February 10, 2022.