December 15, 2025

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

Re: K253677
Trade/Device Name: Tembo Embolic System
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular embolization device
Regulatory Class: Class II
Product Code: KRD
Dated: November 21, 2025
Received: November 21, 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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

FINN E. DONALDSON -S

Digitally signed by FINN E. DONALDSON -S
Date: 2025.12.15 10:51:02 -05'00'

Finn Donaldson
Acting 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)*
K253677

Device Name
Tembo Embolic System

Indications for Use *(Describe)*
The Tembo Embolic System is a gelatin agent intended for use in the embolization of hypervascular tumors and blood vessels to occlude blood flow in the peripheral vasculature.

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.

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 15, 2025

Subject Device:

Proprietary Name:	Tembo Embolic System
Common Name:	Embolization Device
Classification Name:	Device, Vascular, For Promoting Embolization (21 CFR 870.3300, Product Code KRD)
Device Classification:	Class II
Classification Panel:	Cardiovascular

Predicate Device:

Proprietary Name:	TEMBO Embolic System
Manufacturer:	Instylla, Inc.
510(k) Number:	K240873

Device Description:

The Tembo Embolic System consists of biocompatible, dry resorbable particles of porcine gelatin in a 10 mL syringe with a non-vented luer lock cap.

The Tembo Embolic System is a gelatin agent and a sterile, single use, medical device intended for the embolization of hypervascular tumors and blood vessels to occlude blood flow in the peripheral vasculature. The Tembo Embolic System particles are hydrated using commercially available contrast media or contrast mixed with saline. Once hydrated, the material is injected into the target blood vessels via a commercially available microcatheter for occlusion of target vasculature. The dry Tembo Embolic System gelatin particles are between 85 µm and 255 µm and the hydrated gelatin particles are between 150 µm and 450 µm.

Indications for Use:
The Tembo Embolic System is a gelatin agent intended for use in the embolization of hypervascular tumors and blood vessels to occlude blood flow in the peripheral vasculature.

The indications for use statement is identical to the predicate device.

Comparison of Technological Characteristics to the Predicate Device:
The Tembo Embolic System is substantially equivalent in intended use and fundamental technological characteristics to the legally marketed predicate device, TEMBO Embolic System (K240873).

The subject and predicate device differ from one another in packaging. The subject Tembo Embolic System packaging has been designed and constructed to protect the device through sterilization, distribution, handling, and storage. This difference in packaging does not raise any new issues of safety or effectiveness for the subject device as it does not alter the intended use or the technological characteristics of the device when compared to the predicate device.

The indications for use, principle of operation, and technological characteristics remain identical between the subject and predicate device.

Performance Data
Performance testing of the final, sterilized Tembo Embolic System included bench testing and functional testing to verify specifications fundamental to the design of the device. Testing included the following:

- Particle Size – Dry
- Particle Size – Hydrated
- Delivery Ease
- Macroscopic Appearance
- Pepsin Digestion
- pH of Hydrated Gelatin
- Pot Life
- Simulated Use Testing which included testing the following:
    - Ability to Create an Embolization
    - Depth of Penetration
    - Minimal Non-Target Embolization
    - Directed Delivery of Embolic Material
    - Embolic Material Withstands Confirmation Angiography
    - Embolic Delivery Through Microcatheter System
    - Ability to Start and Stop Embolic Delivery
- Compatibility with Female Luer Connections

All performance testing met predetermined specifications. 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 implant device in contact with blood for a long term (>30 days) duration. The gelatin particles are not changing and the packaging updates are non-patient contacting. Therefore, per 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.

The gelatin raw material used in the Tembo Embolic System is compliant with ISO 22442-1 *Medical devices utilizing animal tissues and their derivatives Part 1: Application of risk management*.

Sterility

The Tembo Embolic System is sterilized via a gamma radiation process to a Sterility Assurance Level (SAL) of 10^{-6}, in accordance with ISO 11137-1 *Sterilization of health care products Radiation Part 1: Requirements for developments, validation and routine control of a sterilization proves for medical devices* and ISO 11137-2 *Sterilization of health care products Radiation Part 2: Establishing the sterilization dose*. The Tembo Embolic System modifications were evaluated and sterilization validation was reconducted as the packaging was changed.

A bacterial endotoxin test (BET), also known as the Limulus amebocyte lysate (LAL) test is not being reconducted as no patient contacting material is being modified as part of this modification to the Tembo Embolic System.

Packaging

Packaging testing was conducted on sterilized Tembo Embolic System with modified packaging 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 Tembo Embolic System 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.

Animal Testing

The embolic material remains identical between the subject Tembo Embolic System and the legally marketed predicate device and the modifications to the TEMBO Embolic System are to non-patient contacting material. The animal testing results of the predicate device are representative of the subject device and no additional animal testing needed to be conducted for the subject device.

Conclusion

Instylla has demonstrated that the Tembo Embolic System 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, TEMBO Embolic System, which was cleared under 510(k) Premarket Notification K240873 on December 16, 2024.