December 16, 2024

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

Re: K240873
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 13, 2024
Received: November 13, 2024

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: 2024.12.16 10:50:30 -05'00'

Finn Donaldson
Acting Assistant Director
DHT2C: Division of Coronary and
Peripheral Intervention Devices
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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)*
K240873

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.

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
Sr. Regulatory Affairs Manager
Phone: 781-622-9293
Email: jennyg@instylla.com

Date Prepared:

December 13, 2024

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:	EmboCube™ Embolization Gelatin
Manufacturer:	Biosphere Medical, S.A.
510(k) Number:	K183120

The Gel-Bead Embolization Spheres, cleared under 510(k) Premarket Notification K133237, was used as a reference device in this submission.

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 vessel via a commercially available microcatheter for occlusion of target vasculature. The dry TEMBO Embolic System gelatin particles are between 85 µm and 225 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.

Comparison to Predicate and Reference Device:

The TEMBO Embolic System is similar in design to the predicate device, EmboCube Embolization Gelatin (K183120), as both provide a mechanical barrier to blood flow and are delivered using microcatheters. The TEMBO Embolic System's indications for use are similar to EmboCube's, as it is within the scope of the predicate device's indications for use. They are both intended to embolize hypervascular tumors and blood flow to occlude blood vessels in peripheral vasculature. The subject device contains gelatin and sodium chloride, while the predicate only contains gelatin. The TEMBO Embolic System and EmboCube Embolization Gelatin differ in particle size and shape: the subject device has a dry particle size between 85-255µm and has non-uniform particle shape, while the predicate device has a particle size of 2.5mm and 5mm and has a cube particle shape. The reference device, Gel-Bead Embolization Spheres (K133237), contains similar materials to the subject device and the hydrated TEMBO Embolic System particle size falls within the reference device's particle size ranges.

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:

- Visual Verification
- Particle Size – Dry
- Iodinated Contrast Media Chemical Compatibility
- Delivery Ease
- Embolic Persistence

- 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. Comparative testing was also conducted between the subject and 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 an implant device in contact with blood for a long term (>30 days) duration. The following biocompatibility tests were successfully completed on the final, sterilized TEMBO Embolic System:

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Material Mediated Pyrogenicity
- Subacute Systemic Toxicity
- Implantation
- Genotoxicity
- Hemocompatibility
- Chemical Characterization

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

TEMBO is sterilized via gamma radiation to a Sterility Assurance Level of 10^{-6}, in accordance with ISO 11137-1 *Sterilization of health care products Radiation Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices* and ISO 11137-2 *Sterilization of health care products Radiation Part 2: Establishing the sterilization dose*.

A bacterial endotoxins test (BET), also known as the Limulus amebocyte lysate (LAL) test, was validated to establish that the TEMBO endotoxin level will be <20 endotoxin units (EU)/device.

Shelf Life

TEMBO 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

Instylla has conducted an animal study, on eleven swine, to evaluate the acute embolization effect of the TEMBO Embolic System in the swine kidney via the renal arteries. Additionally, the systemic impact of embolic was monitored during the survival period. The impact of embolization to the target tissue and non-target embolization/device migration was assessed over a period of 28 days.

An additional animal study was conducted on 8 swine to evaluate the embolic effect of TEMBO at 7 days, compared to EmboCube and Gel-Bead as controls.

Conclusion

Instylla has demonstrated that the TEMBO Embolic System is substantially equivalent in fundamental design, function, device materials, sterilization, operating principle, intended use/indication for use and fundamental technology to the legally marketed predicate device, EmboCube™ Embolization Gelatin (K183120) and reference device Gel-Bead Embolization Spheres (K133237).