February 23, 2024

Embolx, Inc.
Louise Musante
Regulatory Compliance Consultant
530 Lakeside Dr. Suite 200
Sunnyvale, California 94085

Re: K232536
Trade/Device Name: Soldier Microcatheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: DQO
Dated: January 18, 2024
Received: January 25, 2024

Dear Louise Musante:

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.

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,

Lydia S. Glaw -S

Digitally signed by Lydia S. Glaw -S
Date: 2024.02.23 20:43:43 -05'00'

Lydia Glaw
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232536

Device Name
Soldier Microcatheter

Indications for Use *(Describe)*
The Soldier Microcatheter is indicated for use in the blood vessels of the peripheral vasculature. It is intended to assist in the delivery of diagnostic agents and therapeutic agents into the target treatment area.

The Soldier Microcatheter is intended for Prescription Use Only.

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
PRAStaff@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."

Section 5 – 510(k) Summary

510(k) Summary
Embolx, Inc.'s
Soldier

DATE PREPARED: February 23, 2024

1. **COMPANY NAME/CONTACT**

Embolx, Inc.
530 Lakeside Dr. #200
Sunnyvale, CA 94085

2. **CONTACT:**

Louise Musante
Regulatory Compliance Consultant
Email: louisemusante@gmail.com
Cell Phone: (650) 242-5563

3. **DEVICE INFORMATION**

Device Trade Name: Soldier Microcatheter
Common Name: Microcatheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Product Code: DQO
Device Class: Class II
510(k) Review Panel: Cardiovascular

4. **PREDICATE DEVICE**

Trade name: Progreat

510(k) submitter/holder: Terumo Medical Corporation

510(k) Numbers: K033583, K170223

5. REFERENCE DEVICE USED IN NON-CLINICAL PERFORMANCE TESTING

Sniper Infusion Catheter with Balloon Occlusion (K180904)

6. DEVICE DESCRIPTION

The Soldier is a single lumen catheter designed to access small, tortuous vasculature. It is available in a variety of outer and inner diameters. Each configuration has a hydrophilic coating to provide lubricity for navigation of vessels. The inner lumen is lined with lubricious PTFE to facilitate movement of guidewires and other devices. The distal tip of the catheter is radiopaque to aid in visualization under fluoroscopy.

7. INDICATION FOR USE STATEMENT

The Soldier Microcatheter is indicated for use in the blood vessels of the peripheral vasculature. It is intended to assist in the delivery of diagnostic agents and therapeutic agents into the target treatment area.

The Soldier Microcatheter is intended for Prescription Use Only.

8. INTENDED USE STATEMENTS:

The Soldier is intended for the infusion of contrast media into all peripheral vessels up to and including the cervical vessels, all vessels in the lower and upper extremities. The Soldier is also intended for drug infusion in intra-arterial therapy and the infusion of embolic materials for hemostasis.

The Soldier is contraindicated for use in the cerebral and coronary vessels. It is not intended for use in embolectomy or angioplasty procedures.

9. SUBSTANTIAL EQUIVALENCE COMPARISON

The Soldier catheter is substantially equivalent to the claimed predicate device; the Progreat catheter (K033583), based on comparisons of the intended use and technological characteristics.

Section 5 – 510(k) Summary

Table 1 – Comparison Table of Subject Device to Predicate Device

Attributes	Soldier (Subject Device)	Progreat Catheter (Predicate Device) *(K033583)*	Differences	Differences raise any additional safety issues?
General Information				
Regulation #	21 CFR 870.1200	21 CFR 870.1200	Same	N/A
Regulation Name	Diagnostic Intravascular Catheter	Diagnostic Intravascular Catheter	Same	N/A
Regulatory Class	Class II	Class II	Same	N/A
Product Code	DQO	DQO	Same	N/A
Indications for Use	The Soldier Microcatheter is indicated for use in the blood vessels of the peripheral vasculature. It is intended to assist in the delivery of diagnostic agents and therapeutic agents into the target treatment area. The Soldier Microcatheter is intended for Prescription Use Only.	The Progreat is intended for the infusion of contrast media into all peripheral vessels up to and including the cervical vessels, all vessels in the lower and upper extremities and all coronary vessels. The Progreat is also intended for drug infusion in intra-arterial therapy and the infusion of embolic materials for hemostasis. The Progreat should not be used in cerebral vessels.	Soldier should not be used in coronary vessels. It is also not intended for use in embolectomy or angioplasty procedures.	No

Table 2 – Comparison Table of Technological Characteristics: Subject Device to Predicate Device

Attributes		Soldier (Subject Device)	Progreat Catheter (Predicate Device) *(K033583)*	Differences	Differences raise any additional safety issues?
Device Specifications					
Catheter	**Catheter Size Fr (mm)**	2.0 Fr (0.67 mm) 2.5 Fr (0.84 mm)	2.0 Fr (0.67 mm) 2.4 Fr (0.80 mm) 2.7 Fr (0.90 mm) 2.8 Fr (0.93 mm)	Dimensions	None
	Catheter OD Distal End Fr (mm)	2.0 Fr (0.67 mm) 2.5 Fr (0.84 mm)	2.0 Fr (0.67 mm) 2.4 Fr (0.80 mm) 2.7 Fr (0.90 mm) 2.8 Fr (0.93 mm)	Dimensions	None

Section 5 – 510(k) Summary

Attributes		Soldier (Subject Device)	Progreat Catheter (Predicate Device) *(K033583)*	Differences	Differences raise any additional safety issues?
	Catheter OD Proximal End Fr (mm)	2.0 Fr (0.67 mm) 2.5 Fr (0.84 mm)	2.7 Fr (0.90 mm) 2.9 Fr (0.97 mm) 2.9 Fr (0.97 mm) 3.0 Fr (1.00 mm)	Dimensions	None
	Maximum OD Fr (mm)	2.5 Fr (0.84 mm) 2.9 Fr (0.97 mm)	2.7 Fr (0.90 mm) 2.9 Fr (0.97 mm) 2.9 Fr (0.97 mm) 3.0 Fr (1.00 mm)	Dimensions	None
	Catheter Effective Lengths	130 cm 155 cm	100 cm 110 cm 130 cm 150 cm	Dimensions	None
	Tip Design	Atraumatic	Atraumatic	None	N/A
	Hub Design	Female Luer, Tapered Funnel Access	Female Luer, Tapered Funnel Access	None	N/A
	Hydrophilic Coating Length (Catheter length/Coating length, *from the distal tip)*	130 cm/ 70 cm 155 cm/ 70 cm	100 cm/ 50 cm 110 cm/ 50 cm 130 cm/ 70 cm 150 cm/ 90 cm	Dimensions	None
	Coating	Hydrophilic Coating	Hydrophilic coating	None	N/A
Guidewire	**Wire Diameter**	Up to 0.018”	Up to 0.021”	Dimensions	None
Accessories		None	Packaged with: Guidewire Guidewire Inserter Catheter Mandrel (stylet) 2.5mL Syringe with Lock Wire Stopper Catheter Stopper XS Hemostatic Valve	Soldier packaged without Accessories	None
General Information					
Design/Construction		Single lumen catheter consisting of metal coil reinforced multi-layer polymer tubing with hydrophilic coating.	Single lumen catheter consisting of metal coil reinforced multi-layer polymer tubing with hydrophilic coating.	None	N/A
Packaging	**Pouch**	Polyester/Polyethylene/ Tyvek*	Unknown	N/A	N/A

Attributes		Soldier (Subject Device)	Progreat Catheter (Predicate Device) *(K033583)*	Differences	Differences raise any additional safety issues?
	Hoop	Polyethylene	Unknown	N/A	N/A
	Display Carton	SBS Paperboard	Unknown	N/A	N/A
	Configuration	Single Use/Disposable	Single Use/Disposable	None	N/A
Sterilization		EtO	EtO	None	N/A
Shelf-life		12 months	24 months	Soldier Shelf Life Validated to 12 Months	No

10. SUMMARY OF TECHNOLOGICAL DIFFERENCES

Indications for Use:

The subject device: Soldier Microcatheter, has been validated for use in the blood vessels of the peripheral vasculature, with the exception of the coronary vessels. It is also not intended for use in embolectomy or angioplasty procedures. The limitations of use for the Soldier Microcatheter are clearly identified as contraindications in the product label. The predicate device: Progreat catheter, has been cleared for use in the peripheral vasculature, including the coronary vessels. It is also cleared for the infusion of embolic materials for hemostasis.

The differences described do not raise any additional safety or efficacy concerns for the subject device as the indications for use of the subject device, falls within the intended use of the cleared predicate device, therefore the two devices have the same intended use.

Dimensions:

The subject device: Soldier Microcatheter, offers fewer catheter configurations than the cleared predicate device: Progreat catheter. However, the catheter sizes, with the exception of the 155 cm length, fall within the largest and smallest catheter dimensions cleared to market for the predicate device. Performance data for the longer catheter length, in addition to the other sizes, support the substantial equivalency claim and therefore do not raise any additional safety or efficacy concerns for the subject device.

Accessories:

The subject device: Soldier Microcatheter, is packaged without accessories, unlike the predicate device: Progreat catheter, which is packaged with a guidewire, a guidewire

inserter, a catheter mandrel (stylet), a 2.5mL syringe with lock, a wire stopper, a catheter stopper XS, and a hemostatic valve. Performance testing for the Soldier Microcatheter was performed using a third-party guidewire without incidence. Device compatibility specifications are outlined in the product labeling. Therefore, the absence of accessories packaged with the subject device, does not raise any additional safety or efficacy concerns for the subject device.

Shelf-life:

The subject device: Soldier Microcatheter, has been validated to a shelf-life of 12-months (1 year) though accelerated aging, which will be included on the product label. The predicate device: Progreat catheter, has been validated to a shelf-life of 24-months (2 years). The difference in shelf-life does not raise any additional safety or efficacy concerns for the subject device.

11. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING

As required under Section 12, Part (a)(i)(3A) of the Safe Medical Devices Act of 1990. A summary of any information regarding substantial equivalence of the device follows.

Included in this section are summary descriptions of the testing which substantiates the performance of the subject device: Soldier Microcatheter as well as its substantial equivalence to the predicate device: Progreat;

- Biocompatibility Testing
- Design Verification (Performance Bench-Top Testing)
- Sterilization Validation
- Shelf-life

a) Biocompatibility Testing

Biocompatibility testing was conducted in accordance with the FDA recognized consensus standard; *ISO 10993-1, Biological Evaluation of Medical Devices, Part 1 Evaluation and Testing within a risk management process* (recognition #2-258), to ensure that patient contact materials are biocompatible for their intended use. All studies were conducted pursuant to 21 CFR, Part 58, Good Laboratory Practices. Testing included the following:

- Cytotoxicity: Cytotoxicity using the ISO L929 MEM Elution Test
- Sensitization: ISO Kligman Maximum Sensitization Test
- Irritation: ISO Intracutaneous Injection Test
- Systemic Toxicity (Acute): ISO Systemic Injection Test, ISO Rabbit Pyrogen Test
- Hemocompatibility: ASTM Partial Thromboplastin Time (PTT) Test; ISO C3a and SC5b-9 Complement Activation Test; ISO Dog Thrombogenicity Study in

Dogs Test
- Chemical/Material Review

Results from each test met the defined acceptance criteria and support compliance to ISO 10993-1, Biological Evaluation of Medical Devices, Part 1 Evaluation and Testing within a risk management process (recognition #2-258).

b) Design Verification (Performance Bench-top Testing)

Performance testing was conducted to ensure the safety and effectiveness of the Soldier Microcatheter and to demonstrate substantial equivalence to the predicate device: Progreat catheter. The following bench tests were:

- Visual Inspection
- Dimensional Verification
- Hub Integrity
- Catheter Burst & Leakage Pressure
- Catheter Flow
- Tensile Strength
- Torsion
- Bend & Buckle ("*flexibility and kink test*")
- Materials Test Report
- Radiopacity ("Radio-detectability")
- Particulate
- Simulated Use in Peripheral Vasculature
- Shipping and Packaging
- Pouch Seal Strength
- Pouch Seal Integrity
- Corrosion Resistance

c) Sterilization

Sterilization of the subject device: Soldier catheter, is performed using ethylene oxide, an established sterilization method, as identified in the FDA guidance; *Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile,* January 21, 2016. The predicate device: Progreat catheter, is also sterilized using ethylene oxide.

All testing data met the defined acceptance criteria for sterility assurance level (SAL), EtO residuals, bacterial endotoxins and material mediated pyrogenicity, in accordance with the FDA recognized consensus standard; *ISO 10993-7:2008, Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals* (recognition #2-275), in addition to other international sterility standards.

d) Shelf-Life

A shelf-life of 12 months (1 year) has been validated though accelerated aging of the subject device: Soldier catheter. The predicate device: Progreat catheter, has been validated to 24 months (2 years). Testing was conducted on final device assemblies, packaged, and sterilized with ethylene oxide. Testing was performed in accordance with the FDA recognized consensus standard; *ASTM F1980:2016: Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices* (recognition # 14-497). All tests met the pre-defined performance criteria.

12. CONCLUSION

Embolx, Inc. believes that the Soldier Microcatheter is substantially equivalent in intended use and technological characteristics to the Progreat catheter (k033583). The Soldier catheter therefore meets the Federal Food, Drug and Cosmetic Act criteria for 510(k) clearance of this device.