April 12, 2022

Boston Scientific Corporation
Heidi Shearer
Senior Regulatory Affairs Specialist
One Scimed Place
Maple Grove, Minnesota 55311

Re: K213398
Trade/Device Name: EMBOLD Fibered Detachable Coil System
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular Embolization Device
Regulatory Class: Class II
Product Code: KRD
Dated: March 11, 2022
Received: March 14, 2022

Dear Heidi Shearer:

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,

Finn Donaldson
Assistant Director (Acting)
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)*
K213398

Device Name
EMBOLD™ Fibered Detachable Coil System

Indications for Use *(Describe)*
The EMBOLD™ Fibered Detachable Coil system is intended to obstruct or reduce rate of blood flow in the peripheral vasculature.

This device is not intended for coronary or neurovascular use.

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."

510(k) Summary

510(K) Summary Complying with 21 CFR 807.92

I. SUBMITTER INFORMATION

Submitter Name: Boston Scientific Corporation

Submitter Address:
One Scimed Place
Maple Grove, MN 55311-1566
USA

Telephone: 763-255-0056
Fax: 763-494-2222
e-mail: Heidi.Shearer@bsci.com

Contact person name: Heidi Shearer
Date Prepared: April 12, 2022

II. DEVICE INFORMATION

Proprietary Name: EMBOLD™ Fibered Detachable Coil System
Tables 1 and 2 below summarize the relevant subject device information.

Table 1: EMBOLD™ Fibered Detachable Coil System UPNs

Universal Product Numbers (UPNs)	Coil Secondary Wind OD (mm)	Coil Length (cm)
M001394240020040	2	4
M001394240020060	2	6
M001394240030060	3	6
M001394240030120	3	12
M001394240040080	4	8
M001394240040150	4	15
M001394240050080	5	8
M001394240050150	5	15
M001394240060100	6	10
M001394240060200	6	20
M001394240080200	8	20
M001394240100200	10	20
M001394240100300	10	30
M001394240100500	10	50
M001394240120200	12	20
M001394240120300	12	30
M001394240120500	12	50
M001394240140200	14	20
M001394240140300	14	30
M001394240140500	14	50
M001394240180500	18	50
M001394240200500	20	50
M001394240220600	22	60
M001394240320600	32	60

Table 2: Additional Device Information

Common or Usual name	Regulatory Number	Regulatory Name	Product Code	Product Code Name	Regulatory Class
Vascular embolic coil system	21 CFR Part 870.3300	Vascular Embolization Device	KRD	Device, Vascular, For Promoting Embolization	II

III. PREDICATE DEVICE IDENTIFICATION

Name of Predicate Device

Interlock™ Fibered IDC™ Occlusion System (K132578, Cleared September 13, 2013)
Predicate device referenced above has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

The EMBOLD™ Fibered Detachable Coil System consists of a delivery wire, removable introducer sheath, and permanent implantable fibered embolic coil. The device is compatible with 0.021 inch to 0.027 inch microcatheters. In addition, the device features a modified mechanical detachment mechanism consisting of an inner pull wire connecting the coil and delivery wire coupler arms, activated by the user through a proximal laser etched outer wire perforation. The delivery wire design allows the coil to be fully advanced, retracted, and deployed prior to final placement.
The EMBOLD™ Fibered Detachable Coil System is provided sterile, using 100% ethylene oxide (EO) gas sterilization, and is intended for hospital and single use only.

Table 3 below provides information on the differences between the EMBOLD™ Fibered Detachable Coil System models, in relation to specific features such as coil secondary OD, length, and shape. The delivery wire and introducer sheath utilize the same design throughout the product matrix.

Table 3: EMBOLD™ Fibered Detachable Coil System Device Features

Coil Secondary Wind OD (mm)	Coil Length (cm)	Coil Shape
2	4	Helical
2	6	
3	6	2-Diameter (2D)
3	12	
4	8	
4	15	
5	8	
5	15	
6	10	
6	20	
8	20	
10	20	
10	30	
10	50	
12	20	
12	30	
12	50	
14	20	
14	30	
14	50	
18	50	
20	50	

Coil Secondary Wind OD (mm)	Coil Length (cm)	Coil Shape
22	60	
32	60	

V. INTENDED USE AND INDICATION FOR USE

Predicate and subject device intended use/indication for use is the same.

EMBOLD™ Fibered Detachable Coil System Intended Use / Indication for Use
The EMBOLD™ Fibered Detachable Coil system is intended to obstruct or reduce rate of blood flow in the peripheral vasculature. This device is not intended for coronary or neurovascular use.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The EMBOLD™ Fibered Detachable Coil System has similar technological characteristics to the predicate device as shown in the table below.

Characteristic	Subject Device EMBOLD™ Fibered Detachable Coil System	Predicate Device Interlock™ Fibered IDC™ Occlusion System (K132578)	Comparison
Coil Primary Wind OD (inches)	0.015	0.012	**SIMILAR** Minimal dimensional differences support additional microcatheter compatibility.
Microcatheter Compatibility (inches)	0.021 (0.53mm) to 0.027 (0.6mm)	0.0021 (0.53mm)	
Coil Lengths (cm)	4-60	4-60	**SAME**
Secondary Coil OD (mm)	2-32	2-22	**SIMILAR** Additional OD treats same anatomy as predicate.
Coil Shapes	2mm: Helical 3-32mm: 2D	2-22mm: 2D	**SIMILAR** Helical loops same as 2D, with no smaller loops.
Delivery Wire Length	177cm effective length	175cm effective length	**SIMILAR** Subject device delivered through same standard microcatheter lengths as predicate.
Coil Detachment Mechanism	Mechanical, user activated, interlocking coupler arms detach when outside of microcatheter and when user manually retracts inner pull wire from coupler arms	Mechanical, user activated, interlocking coupler arms detach when pushed out of microcatheter	**SIMILAR** Same mechanical detachment with coupler arm separation, with additional feature.
Introducer Sheath	1 length Reinforced tapered tip Separate lock component	2 lengths Tapered tip Integrated lock	**SIMILAR** Same function as predicate with modifications to align with EMBOLD Fibered

Characteristic	Subject Device EMBOLD™ Fibered Detachable Coil System	Predicate Device Interlock™ Fibered IDC™ Occlusion System (K132578)	Comparison
			minor dimensional differences.
MRI Compatibility	MR Conditional	MR Conditional	**SAME**
Sterilization Method	EO	EO	**SAME**
SAL	10^{-6}	10^{-6}	**SAME**
Coil Materials	Platinum /Tungsten alloy coil Metal alloy coil coupler arm Synthetic fibers	Platinum /Tungsten alloy coil Metal alloy coil coupler arm Synthetic fibers	**SAME**
Delivery Wire Materials	Metal and polymer materials Metal alloy delivery wire coupler arm	Metal and polymer materials Metal alloy delivery wire coupler arm	**SIMILAR** Basic delivery function is the same as the predicate with material differences to facilitate detachment and microcatheter compatibility.
Packaging Materials and Configuration	Package holds one EMBOLD Fibered device. No RHV is included. Sterile package contained in shelf carton. An eIFU exists for the EMBOLD Fibered product. No physical IFU included with package.	Package holds one Interlock Fibered IDC device. RHV is included inside sterile barrier. Sterile package and paper IFU contained in shelf carton.	**SIMILAR** The RHV is no longer provided with the device as available through ancillary devices or hospital. The IFU is available outside the package configuration.

VII. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING

A full suite of biocompatibility testing, bench testing, and an acute GLP animal study were performed to support a determination of substantial equivalence between the EMBOLD™ Fibered Detachable Coil System and the predicate Interlock™ Fibered IDC™ Occlusion System (K132578). The results of these tests provide reasonable assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use. No new safety or effectiveness issues were raised during the device testing.

VIII. CONCLUSION

Based on the intended use, technological characteristics, and the safety and performance data provided, the EMBOLD™ Fibered Detachable Coil System is considered appropriate for the intended use and substantially equivalent to the predicate device. The subject device technological and material differences do not raise new questions of safety or effectiveness, and the subject devices are substantially equivalent to the predicate Interlock™ Fibered IDC™ Occlusion System (K132578).