June 27, 2023

Boston Scientific Corporation
Laura Judge
Regulatory Affairs Specialist
300 Boston Scientific Way
Marlborough
Boston, Massachusetts 01752

Re: K230706
Trade/Device Name: EMBOLD™ Soft Detachable Coil System
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular Embolization Device
Regulatory Class: Class II
Product Code: KRD
Dated: May 26, 2023
Received: May 26, 2023

Dear Laura Judge:

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,

Misti L. Malone -S

Misti Malone, PhD
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)*
K230706

Device Name
EMBOLD™ Soft Detachable Coil System and EMBOLD™ Packing Detachable Coil System

Indications for Use *(Describe)*
The EMBOLD™ Soft Detachable Coil System and EMBOLD™ Packing 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.

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510(k) Summary

I. SUBMITTER INFORMATION

Submitter Name: Boston Scientific Corporation

Submitter Address:
300 Boston Scientific Way Marlborough,
Boston, MA 01752, USA

Telephone: 353 (86) 177 7184
Email: Laura.Judge@bsci.com

Contact person name: Laura Judge
Date Prepared: March 14, 2023

II. 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

EMBOLD™ Fibered Detachable Coil System (K213398, Cleared April 12, 2022)
Predicate device referenced above has not been subject to a design-related recall.

Reference Devices:

- IDC™ Interlocking Detachable Coil (K141378, Cleared 08 October 2014)
- Interlock™ -35 Fibered IDC Occlusion System (K133208, Cleared 14 November 2013
- Penumbra's Occlusion Device (POD®) Packing Coil (K170852, Cleared 19 July 2017).

Reference devices listed above have not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

The EMBOLD™ Soft Detachable Coil System and EMBOLD™ Packing Detachable Coil System consists of a delivery wire, removable introducer sheath, and permanent implantable non-fibered embolic coil. The EMBOLD™ Soft coil can be delivered to challenging peripheral anatomy, and the EMBOLD™ Packing coil is highly conformable to enable dense packing. The device is compatible with 0.021 inch to 0.027-inch microcatheters. In addition, the device features a 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™ Soft and EMBOLD™ Packing Detachable Coil System is provided sterile, using 100% ethylene oxide (EO) gas sterilization, and is intended for hospital and single use only.

V. INDICATIONS FOR USE

The EMBOLD™ Soft Detachable Coil System and EMBOLD™ Packing 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.

Predicate and subject devices intended uses are the same.

Subject Device EMBOLD™ SOFT Detachable Coil System Intended Use and Indications for Use	***Subject Device*** EMBOLD™ PACKING Detachable Coil Intended Use and Indications for Use	***Predicate Device*** EMBOLD™ FIBERED Detachable Coil Intended Use and Indications for Use
Intended Use/Indications for Use The EMBOLD Soft Detachable Coil System is indicated to obstruct or reduce rate of blood flow in the peripheral vasculature. This device is not intended for coronary or neurovascular use.	**Intended Use/Indications for Use** The EMBOLD Packing Detachable Coil System is indicated to obstruct or reduce rate of blood flow in the peripheral vasculature. This device is not intended for coronary or neurovascular use.	**Intended Use/Indications 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 WITH THE PREDICATE DEVICE

The EMBOLD™ Soft Detachable Coil System and EMBOLD™ Packing Detachable Coil System incorporate substantially equivalent device materials and design, packaging materials and design, fundamental technology, manufacturing processes, sterilization process and intended use as those featured in the predicate device, EMBOLD™ Fibered Detachable Coil system, K213398.

Similar to the predicate Embold™ Fibered Detachable Coil System, the subject device consists of a delivery wire with an implantable platinum/tungsten coil attached at the distal end with platinum/iridium alloy coupler arms contained within an introducer sheath which also allow smooth delivery of the coil system through 0.021 inch to 0.027-inch microcatheters. EMBOLD Soft and EMBOLD Packing have the same mechanical, user-activated, detachment mechanism as the predicate device. The subject device features a non-fibered, coil implant with a stretch-resistant feature.

The following technological differences exist between the subject and predicate devices:

- Packing Coil Shape
- Non-Fibered Coil

Differences in technological characteristics between the subject and predicate devices do not raise different questions of safety and effectiveness. The results of bench testing provide reasonable assurance of substantial equivalence of the EMBOLD Soft Detachable Coil System and EMBOLD Packing Detachable Coil System with the predicate device (K213398).

VII. PERFORMANCE DATA

The EMBOLD™ Soft Detachable Coil system and EMBOLD™ Packing Detachable Coil System were subjected to testing according to the requirements of Guidance for Industry and FDA Staff-Class II Special Controls

Document: Vascular and Neurovascular Embolization Devices (December 29, 2004). Bench, animal and biocompatibility testing in accordance with ISO 10993 were performed to support a determination of substantial equivalence. 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 performance issues were raised during the testing; therefore, this device is substantially equivalent to the predicate device.

VIII. **CONCLUSIONS**

Based on the intended use, technological characteristics, and the safety and performance data provided, the Embold™ Soft Detachable Coil System and Embold™ Packing Detachable Coil System is considered appropriate for the intended use and substantially equivalent to the predicate device. The subject device's technological and material differences do not raise new questions of safety or effectiveness, and the subject devices are as safe and effective as the predicate Embold ™ Fibered Detachable Coil System (K213398).