October 3, 2024

Boston Scientific
Heidi Shearer
Regulatory Affairs Specialist
1 Scimed Place
Maple Grove, Minnesota 55311

Re: K242507
Trade/Device Name: OBSIDIO™ Conformable Embolic
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular Embolization Device
Regulatory Class: Class II
Product Code: KRD
Dated: August 22, 2024
Received: September 24, 2024

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 (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: 2024.10.03 16:05:24 -04'00'

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)*
K242507

Device Name
Obsidio Conformable Embolic

Indications for Use *(Describe)*
Obsidio Conformable Embolic is indicated for use in the embolization of:
• Hypervascular tumors,
• Blood vessels to occlude blood flow for controlling bleeding/hemorrhaging 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.

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
e-mail: Heidi.Shearer@bsci.com
Contact person name: Heidi Shearer

Date Prepared: August 22, 2024

II. DEVICE INFORMATION

OBSIDIO™ Conformable Embolic, UPN M0013972101010

Table 1: Device Information

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

III. PREDICATE DEVICE IDENTIFICATION

Name of Predicate Device

OBSIDIO™ Conformable Embolic (K213385, Cleared July 1, 2022)

IV. DEVICE DESCRIPTION

The OBSIDIO™ Conformable Embolic is a premixed embolic agent consisting of pre-hydrated gelatin and layered silicate, and tantalum powder (to provide for visualization under fluoroscopy). Obsidio Embolic is delivered directly through a microcatheter into the blood vessel to block blood flow to target tissue without relying on precipitation or polymerization. The material conforms to the shape of the vessel. Obsidio Embolic is packaged in a 1 mL (1 cc) syringe. The device is supplied as a sterile, single use product.

V. INDICATIONS FOR USE

Predicate and subject device intended use / indications for use are the same.

Intended Use / Indications for Use

The OBSIDIO™ Conformable Embolic is indicated for use in the embolization of:

- Hypervascular tumors
- Blood vessels to occlude blood flow for controlling bleeding/hemorrhaging in the peripheral vasculature

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The subject and predicate OBSIDIO™ Conformable Embolic have the same technical characteristics. The device is an implantable peripheral vascular embolization device composed of pre-hydrated gelatin, layered silicate, tantalum, and water. The material is contained in a 1 mL syringe and supplied as a sterile, single use product within one sterile barrier peelable pouch per shelf carton.

VII. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING

Use characterization analysis was used to support labeling updates with added use instructions and warnings to enhance safe and effective use of the subject OBSIDIO™ Conformable Embolic. 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

This 510(k) was submitted to implement labeling updates as part of mitigations for a recent Class I Recall. Based on the intended use, technological characteristics, and the use characterization analysis data provided, the subject OBSIDIO™ Conformable Embolic with proposed labeling updates is substantially equivalent to the predicate OBSIDIO™ Conformable Embolic device (K213385).