May 15, 2025

Embolization Inc.
% Melissa Brookshier
Directory of Quality and Regulatory Affairs
Boulder BioMed, Inc.
5421 Western Ave.
Boulder, Colorado 80301

Re: K250276
Trade/Device Name: Nitinol Enhanced Device (NED)
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular Embolization Device
Regulatory Class: Class II
Product Code: KRD
Dated: May 2, 2025
Received: May 5, 2025

Dear Melissa Brookshier:

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,

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250276

Device Name
Nitinol Enhanced Device (NED)

Indications for Use *(Describe)*
The Nitinol Enhanced Device (NED) is intended for arterial and venous embolization in the peripheral vasculature. This device is not intended for 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.

510(K) SUMMARY
NITINOL ENHANCED DEVICE (NED)

1. SUBMISSION SPONSOR

Company Name: Embolization, Inc.
Address: 5421 Western Avenue, Boulder, CO 80301
Contact: James Frank Kasic, II
Title: CEO

2. SUBMISSION CORRESPONDENT

Boulder iQ, Inc.
5421 Western Avenue
Boulder, CO 80301

Office Phone: 303-531-1238 x726

Contact: Melissa Brookshier

Title: Directory of Quality and Regulatory Affairs

3. DATE PREPARED

April 1, 2025

4. DEVICE IDENTIFICATION

Trade/Proprietary Name: Nitinol Enhanced Device (NED)

Common/Usual Name: Vascular embolization device

Classification Name: Vascular embolization device

Regulation Number: 21CFR §870.3300

Product Code: KRD

Device Class: Class II

Classification Panel: Cardiovascular

5. Legally Marketed Predicate / Reference Devices

Predicate Device: K132578 - Interlock-18 Fibered Interlocking Detachable Coil (IDC) Occlusion System (Boston Scientific Corporation)

Reference Device: K141378 - IDC Interlocking Detachable Coil (Boston Scientific Corporation)

6. Indications for Use

The Nitinol Enhanced Device (NED) system is intended for arterial and venous embolization in the peripheral vasculature. This device is not intended for neurovascular use.

7. Device Description

The NED system is comprised of polymer-based occlusion devices intended for embolization procedures in 3-6 mm vessels of the peripheral vasculature. It is intended to be used with 0.027" labeled microcatheters. The NED consists of three components: the NED implants (framing and packing), the delivery system, which is supplied engaged with the implant, and the transfer/removal tool.

The NED framing and packing implants are permanently implanted and include a 0.016" diameter polymer filament which compacts upon delivery. The implants work together to obstruct blood flow in the vessel. The framing implant is deployed first to form the initial pack and create a backing for additional implants to be deployed in accordance with physician discretion. The deployment of the framing implant is followed by the deployment of packing implants, the quantity of which is determined by the physician based on vessel size and occlusion. The physician also has the option to finish the implant pack with another framing implant. The UHMWPE braid on the implants and the nylon 6,6 tails on the packing implant provide a scaffold for thrombus to form and attach. The combination of the mechanical obstruction of blood flow and the formation of thrombus result in vessel occlusion.

The delivery system is comprised of two components: the implant pusher and the introducer. The NED delivery system comes with the NED implant pre-loaded in its package, sterile and ready for use. The pusher is a 180 cm long 0.022" diameter single super-elastic nitinol wire with a 30 cm PTFE jacket and a platinum/iridium radiopaque marker near its distal end. The nitinol pusher coupler is located on the distal end of the pusher, which as described above, serves to engage with the coupler on the implant's proximal end. The NED pusher allows the physician to reposition the NED to ensure preferred vessel positioning prior to detachment. Further, the detachment mechanism provides the physician the ability to completely withdraw the NED before detachment, should a condition result that necessitates its removal. The introducer is a PTFE tube used to protect the implant and maintain coupling between the implant and pusher prior to use (as described in Section 2.1). Once the implant and pusher are transferred into the delivery microcatheter, the introducer is discarded.

The transfer/removal tool is a disposable accessory included with the device that attaches to the hub of the delivery microcatheter prior to inserting the implant. The purpose of the transfer/removal tool is to facilitate the transfer of the implant from the device introducer

into the delivery microcatheter hub and to facilitate the removal of the implant from the delivery microcatheter if necessary. The transfer/removal tool is designed to fit 0.027" labeled microcatheters. The tool is comprised of an ABS and PC Luer adapter assembly bonded with medical grade Dymax 1162-M UV adhesive. The tool utilizes a spring-loaded 300 series stainless steel tube to form the lumen.

8. SUBSTANTIAL EQUIVALENCE DISCUSSION

The following table compares the Nitinol Enhanced Device (NED) to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance testing. The comparison of the devices provides more detailed information regarding the basis for the determination of substantial equivalence.

	Embolization, Inc. NED (Subject Device)	**Boston Scientific Interlock-18 Fibered IDC Occlusion System (Predicate)**	**Boston Scientific IDC Interlocking Detachable Coil (Reference Device)**	**Comparison to Predicate**
510(k) Number	K250276	K132578	K141378	N/A
Regulation Number	21 CFR §870.3300	21 CFR §870.3300	21 CFR §870.3300	Identical to Predicate and Reference Devices
Product Code	KRD	KRD	KRD	Identical to Predicate and Reference Devices
Classification	Class II	Class II	Class II	Identical to Predicate and Reference Devices
Intended Use	Embolization in the peripheral vasculature	Embolization in the Peripheral vasculature	Embolization in the peripheral vasculature	Identical to Predicate and Reference Devices
Indications for Use	The NED is intended for arterial and venous embolization in the peripheral vasculature. This device is not intended for neurovascular use.	The Interlock-18 Fibered ID Occlusion System is indicated to obstruct or reduce the rate of blood flow in the peripheral vasculature. This device is not intended for neurovascular use.	The IDC Coil is a modified interlocking detachable coil indicated to obstruct or reduce rate of blood flow in the peripheral vasculature. This device is not intended for neurovascular use.	Substantially Equivalent to Predicate Device

	Embolization, Inc. NED (Subject Device)	Boston Scientific Interlock-18 Fibered IDC Occlusion System (Predicate)	Boston Scientific IDC Interlocking Detachable Coil (Reference Device)	Comparison to Predicate
Components	Implants (Framing and Packing), Delivery System and Transfer/ Removal Tool	Implant and Delivery System	Implant (to supplement previously deployed Interlock-18 implants in same procedure)	Substantially Equivalent to Predicate Device For Use with IDC Coil Reference Device
Implant Material	Framing implant: Radiopaque polymer, UHMWPE external braid, nitinol, PET atraumatic tip Packing implant: Radiopaque polymer with thrombogenic tails, UHMWPE external braid, PET atraumatic tip	Platinum with thrombogenic tails	Platinum-tungsten alloy	Substantially Equivalent to Predicate Device
Thrombogenic Fibers?	Yes	Yes	No	Identical to Predicate Device
Device Length	Framing implant: 6, 10, and 15 cm Packing implant: 14 cm	2.3, 4, 4.1, 5.8, 6, 8, 10, 12, 15, 20, 30, 50, 60 cm	2-12cm, various diameters	Substantially Equivalent to Predicate Device
Target Vessel/ Implant Curl Diameter	3-4, 4-5, 5-6 mm	2, 3, 4, 5, 6, 8, 10, 12, 14, 18, 20, 22 mm	N/A	Substantially Equivalent to Predicate Device

	Embolization, Inc. NED (Subject Device)	Boston Scientific Interlock-18 Fibered IDC Occlusion System (Predicate)	Boston Scientific IDC Interlocking Detachable Coil (Reference Device)	Comparison to Predicate
Delivery Microcatheter/ Sheath ID	0.027”	0.021”	0.021”	Substantially Equivalent to Predicate Device
Detachment Method	Interlocking arms detach when past catheter tip	Interlocking arms detach when past catheter tip	Interlocking arms detach when past catheter tip	Identical to Predicate and Reference Devices
Single-Use?	Yes	Yes	Yes	Identical to Predicate and Reference Devices
MR Cond Up to 3.0 Tesla?	Yes	Yes	Unknown	Identical to Predicate Device

9. NON-CLINICAL PERFORMANCE DATA

The NED meets all the requirements for overall design, sterilization, and biocompatibility.

The NED passed all the testing in accordance with internal requirements, FDA Guidance, national standards, and international standards shown below to support substantial equivalence of the subject device:

- Nitinol Corrosion Testing (ASTM F2129 and ASTM F3044)
- Product Evaluation for Sharp Edges
- Chemical Characterization of Materials, including Metals Analysis by Inductively Coupled Plasma Mass Spectrometry, Semi-Volatile and Amenable Non-Volatile Organic Compounds by Gas Chromatography/ Mass Spectrometry, Non-Volatile Organic Compounds Semi-Quantitative Scan by Liquid Chromatography/Mass Spectrometry, and Volatile Organic Compounds by Headspace Gas Chromatography/ Mass Spectrometry, and Toxicological Risk Assessment
- Biocompatibility evaluation per ISO 10993-1
- Successful Deployment
- Ease of Delivery
- Delivery and Deployment Force Testing
- Retraction Force Testing
- Detachment Mechanism Testing
- Vessel Distension Measurement
- Compatibility with Delivery Catheters
- Visual Inspection Post-deployment
- End-to-End Tensile Strength
- Radiopacity Test
- Implant with Delivery System Removal Test
- Nitinol Corrosion Test
- Implant Retrieval Test
- Fiber Pull-Out Force
- MRI Compatibility
- CT Artifact Evaluation
- GLP Safety Study (Acute Ovine Study)
- GLP Subchronic Ovine Product Validation Study
- Packaging Integrity
- Shelf Life Validation (packaging and device)

10. CLINICAL PERFORMANCE DATA

No human clinical testing was required to support the NED as the indications for use are equivalent to the predicate device the Interlock-18 Fibered Interlocking Detachable Coil (IDC)

Occlusion System. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

11. STATEMENT OF SUBSTANTIAL EQUIVALENCE

The Nitinol Enhanced Device (NED), as designed and manufactured, is determined to be substantially equivalent to the predicate device, the Interlock-18 Fibered Interlocking Detachable Coil (IDC) Occlusion System.