July 25, 2019

Abbott Vascular
Namratha Manthani
Regulatory Affairs Manager
3200 Lakeside Drive
Santa Clara, California 95054

Re: K191173
Trade/Device Name: Emboshield NAV^6 Embolic Protection System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NTE
Dated: April 29, 2019
Received: May 1, 2019

Dear Ms. Manthani:

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 Malone
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191173

Device Name
Emboshield NAV^6 Embolic Protection System

Indications for Use *(Describe)*
The Emboshield NAV^6 Embolic Protection System is indicated for use as a guide wire and embolic protection system to contain and remove embolic material (thrombus / debris) while performing angioplasty and stenting procedures in carotid arteries and while performing atherectomy, during standalone procedures or together with PTA and/or stenting, in lower extremity arteries. The diameter of the artery at the site of the Filtration Element placement should be between 2.5 and 7.0 mm.

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.

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510(k) Summary

The 510(k) Summary is submitted in accordance with 21 CFR 807.92 and the requirements of the Safe Medical Device Act (SMDA) of 1990.

1. Submitter Information

Submitter's Name	Abbott Vascular
Submitter's Address	3200 Lakeside Drive, Santa Clara, Ca 95054
Telephone	(408) 845-0734
Fax	(408) 845-3743
Contact Person	Namratha Manthani
Date Prepared	July 3, 2019

2. Subject Device

Device Trade Name	Emboshield NAV^6 Embolic Protection System
Device Common Name	Embolic Protection System
Device Classification Name	Catheter, Carotid, Temporary, for Embolization Capture

3. Predicate Device

Device Trade Name	Emboshield NAV^6 Embolic Protection System
510(k) Number	K141678
510(k) Clearance Date	July 22, 2014

4. Device Description

The Emboshield NAV^6 Embolic Protection System (EPS) is a temporary percutaneous transluminal filtration system designed to capture embolic material released during interventional procedures within carotid arteries or atherectomy in the arterial vasculature of the lower extremity. The system consists of the following components: BareWire Filter Delivery Wire, RX Delivery Catheter, Filtration Element and RX Retrieval Catheter and ancillary items which include loading funnel, flushing syringes, introducer tool and torque devices.

5. Indications for Use

The Emboshield NAV^6 Embolic Protection System is indicated for use as a guidewire and embolic protection system to contain and remove embolic material (thrombus/debris) while performing angioplasty and stenting procedures in carotid arteries and while performing atherectomy, during standalone procedures or together with PTA and/or stenting, in lower extremity arteries. The diameter of the artery at the site of the Filtration Element placement should be between 2.5 and 7.0 mm.

6. Technological Characteristics and Substantial equivalence

The subject Emboshield NAV^6 EPS is identical to the currently marketed predicate device except for the changes listed below.

The changes made to the subject Emboshield NAV^6 EPS are:

- Expansion of indication to include use while performing atherectomy in lower extremity arteries (LEA) and
- Additional IFU updates to contraindications, warnings, precautions and adverse events

A comparison between the subject Emboshield NAV^6 EPS and its predicate was performed to support a substantial equivalence determination. The substantial equivalence comparison included the device's intended use, system components, technological characteristics, sterilization, materials and biocompatibility. The conclusion of the comparison analysis is that the subject Emboshield NAV^6 EPS is substantially equivalent to the predicate device.

7. Performance Data

To demonstrate substantial equivalence of the subject Emboshield NAV^6 EPS to the predicate device for the expansion of the indication to lower extremity arteries, non-clinical and clinical assessments were performed.

For the additional labeling changes, no additional performance data was required, as these changes only modify and add content to the IFU without any impact to the operation and/or the performance of the device.

7.1 Non-Clinical Data

To demonstrate substantial equivalence of the subject Emboshield NAV^6 EPS to the predicate device, technological characteristics and performance criteria were evaluated. An assessment of testing to be repeated was performed in accordance with the Guidance for Industry and FDA Staff - *Coronary and Carotid Embolic Protection Devices -Premarket Notification [510(k)] Submissions* (Document Issued on: February 15, 2008) The assessment concluded that the following tests should be performed:

- Deployment and Retrieval Force Test
- Simulated Use

In addition, a study was performed to quantify the tortuosity along the device pathway for endovascular therapy involving the carotid arteries and lower extremity region. The comparison of tortuosity between carotid and lower extremity regions was made using computed tomography angiography (CTA) data from existing patients.

7.2 Clinical Data

To support an indication expansion to include LEA use, clinical data in a real-world population of peripheral arterial disease (PAD) patients treated for lower extremity lesions with atherectomy and an embolic protection device in routine clinical practice at the Mount Sinai Health Center

was analyzed (Emboshield NAV^6 EPS, n=162). The patient population evaluated was representative of complex PAD with a high degree of commonly associated comorbidities. To assess the safety and efficacy of Emboshield NAV^6 EPS in this anatomy, a composite rate of major adverse events (MAE) was calculated. MAE is defined as a composite of death, myocardial infarction (MI), thrombosis, dissection (grade C or greater), distal embolization (DE), perforation at the level of the filter, unplanned amputation and target vessel revascularization (TVR). The primary analysis outcome of freedom from MAE was compared against a performance goal (PG) of 83%, derived from the performance of similar devices in the same anatomy.

The 30-day freedom from MAE rate for Emboshield NAV^6 EPS was 92.0%, in which the lower limit of the two-sided 95% confidence interval was 86.7%, meeting the pre-specified PG of 83%. The MAEs that occurred included one death, two MIs, one thrombosis, eight dissections, and one DE. The MAE rate contains several components and reflects the success and/or complications of the overall procedure and less directly information about the performance of the filter itself. The most commonly observed issues with filters are the likelihood that emboli may escape the filter or the device itself might knock emboli loose and result in DE and associated outcomes. Therefore, occurrence of DE, perforation at the level of the filter, and subsequent unplanned amputation best reflect the performance of the filter. Of the MAE components that are considered most relevant to the evaluation of Emboshield NAV^6 EPS, there was one case of DE and no cases of perforation at the level of the filter and no unplanned amputations.

In the analysis of real-world Emboshield NAV^6 EPS data, the freedom of MAE rate met the pre-specified PG. The patients evaluated showed few adverse events related to filter performance. The patients in this analysis represent a real-world population of PAD with associated comorbidities. Their complex lesions were treated in routine clinical practice and all treatment decisions were made per operator discretion. Thus, this data represents real-world Emboshield NAV^6 EPS usage in the treatment of femoral popliteal lesions.

The clinical and non-clinical data demonstrate that the subject Emboshield NAV^6 EPS met all acceptance criteria and performed similarly to the predicate device and that no new safety or effectiveness issues were raised. Therefore, the subject Emboshield NAV^6 EPS can be considered substantially equivalent to the predicate device.

8. Conclusions

Based on the intended use, system components, technological characteristics, sterilization, materials and biocompatibility and performance data included in this submission, Abbott Vascular considers the subject Emboshield NAV^6 EPS to be substantially equivalent to the currently marketed Emboshield NAV^6 EPS (K141678).