May 23, 2019

Shape Memory Medical
Meghan Reu
Quality and Regulatory Manager
807 Aldo Avenue, Suite 109
Santa Clara, California 95054

Re: K182390
Trade/Device Name: IMPEDE-FX Embolization Plug
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular embolization device
Regulatory Class: Class II
Product Code: KRD
Dated: April 25, 2019
Received: April 26, 2019

Dear Meghan Reu:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Kenneth Cavanaugh
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)*
K182390

Device Name
IMPEDE-FX Embolization Plug

Indications for Use *(Describe)*
The IMPEDE-FX Embolization Plug is indicated for use with the IMPEDE Embolization Plug to obstruct or reduce the rate of blood flow 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.

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"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

SUBMITTER
Shape Memory Medical Inc
807 Aldo Avenue, Suite 109
Santa Clara, CA 95054

Contact Person: Meghan Reu, Quality and Regulatory Sr. Manager
Phone: 408-649-5175 x 711
Fax: 669-230-5932
Date Prepared: March 29, 2019

DEVICE
Name of Device: IMPEDE-FX Embolization Plug
Common Name: Vascular Embolization Device
Classification Name: Device, embolization, arterial
Regulatory Class: Class II, 21 CFR 870.3300
Product Code: KRD

PREDICATE DEVICE
IMPEDE Embolization Plug (K181051)

REFERENCE DEVICE
Vascular Solutions Gel Block Embolization Pledgets (K113266)

DEVICE DESCRIPTION
The IMPEDE-FX Embolization Plug is a permanent implant, pushable embolization device comprised of a porous, degradable polyurethane thermoset foam plug and a proximal platinum-iridium alloy marker band. The foam plug is crimped into a secondary shape to allow delivery through a catheter to the target vessel using a guidewire. Upon deployment in the target vessel and exposure to an aqueous environment and body temperature, the plug will self-expand to its primary shape to embolize the target vessel. The IMPEDE-FX device may only be used in conjunction with the IMPEDE® Embolization Plug System to further enhance vessel occlusion or increase the length of occlusion within the target vessel. It is indicated to obstruct or reduce the rate of blood flow in the peripheral vasculature.

The IMPEDE-FX polyurethane foam undergoes slow oxidative degradation with the majority (> 90%) of the foam remaining at 30 days in a swine intravascular model. The amount of foam degradation was also assessed in vivo in 180-day rat subcutaneous implants and 26-week rabbit intramuscular implants. Analysis of the histology slides from both studies revealed near complete degradation of the polymer foam at the majority of the implant sites in each study.

The device is pre-loaded into an introducer sheath which is made of a PEEK tube bonded to a polycarbonate luer hub to facilitate the transfer of the device into the catheter. The device implant is categorized as a permanent implant, blood contacting device, and the introducer is categorized as an external communicating device, limited (< 24 hour) circulating blood

contacting device. The assembled unit is supplied to the user e-beam sterile for single use.

INDICATIONS FOR USE

The IMPEDE-FX Embolization Plug is indicated for use with the IMPEDE Embolization Plug to obstruct or reduce the rate of blood flow in the peripheral vasculature.

COMPARSON OF TECHNOLOGICAL CHARACTERSTICS WITH THE PREDICATE DEVICE

Transcatheter embolization of the peripheral vasculature is the technological principle for both the subject and predicate devices. It is based on the method of delivering an implant device through a catheter and deploying it into and filling the target site thereby obstructing or reducing blood flow to the vasculature. The following table shows the technological similarities and differences between the subject and predicate device:

TABLE 1: PREDICATE DEVICE COMPARISON CHART

	IMPEDE-FX Embolization Plug	**IMPEDE™ Embolization Plug**
510(k) Number	K182390	K181051
Indications for Use	The IMPEDE-FX Embolization Plug is indicated for use with the IMPEDE Embolization Plug to obstruct or reduce the rate of blood flow in the peripheral vasculature	The IMPEDE Embolization Plug is indicated to obstruct or reduce the rate of blood flow in the peripheral vasculature
Implant Dimensions OD (mm) x L (mm)	IMP-FX-06: 6 x 10 IMP-FX-08: 8 x 10 IMP-FX-12: 12 x 15	IMP-05: 6 x 10 IMP-07: 8 x 10 IMP-12: 12 x 15
Vessel Indication	Not stated in the IFU	2-10mm (3 models)
Product Code	21 CFR 870.330 (KRD)	21 CFR 870.330 (KRD)
Classification	Class II	Class II
Delivery/Deployment Method	Pushable by guidewire through an 0.038" (IMP-FX-06), 0.055' (IMP-FX-08) or 0.070" (IMP-FX-12) Min Catheter ID	Pushable by guidewire through an 0.038" (IMP-05), 0.055' (IMP-07) or 0.070" (IMP-10) Min Catheter ID
How transferred to catheter	The plug implant is pre-loaded in PEEK Introducer Sheath with polycarbonate luer hub; transferred to the catheter by advancing an off the shelf guidewire	The plug implant is pre-loaded in PEEK Introducer Sheath with polycarbonate luer hub; transferred to the catheter by advancing an off the shelf guidewire
Detachment	No - Pushable	No - Pushable
Implant Materials	Polyurethane (polymer foam), Pt/Ir markerband, Adhesive	Polyurethane (polymer foam), Nitinol Core Wire, Pt/Ir Coil, Pt/Ir markerband, Adhesive
Anchoring Mechanism	N/A	Pt/Ir and Nitinol Anchor Coil
How Provided	Sterile, single-use, pre-loaded in introducer	Sterile, single-use, pre-loaded in introducer
Sterilization Method	E-Beam	E-Beam
Biodegradable	Yes – slow degradation with the majority (>90%) of the foam remaining after 30 days in a swine intravascular occlusion animal model. Near complete degradation in 180-day rat subcutaneous implants and 26-week rabbit intramuscular implants	Yes – slow degradation with the majority (>90%) of the foam remaining after 30 days in a swine intravascular occlusion animal model. Near complete degradation in 180-day rat subcutaneous implants and 26-week rabbit intramuscular implants
Radiopacity	Proximal Pt/Ir Marker Band	Proximal Pt/Ir Marker Band and distal Pt/Ir and Nitinol Anchor Coil

PERFORMANCE DATA - NEW

The following performance data were provided in support of the substantial equivalence determination.

Mechanical, Visual and Characterization testing

- Simulated use testing
  - Accessory Compatibility (Guidewire, Catheter and Introducer)
  - Delivery Performance (Deliverability, Migration)
  - Implantation Performance (Plug Expansion, Migration, Bond Integrity)
- Radial Force
- Dimensional Inspection
- Visual Inspection

Animal Study

The IMPEDE-FX Embolization Plug was evaluated acutely (i.e. 4 hour sacrifice) in a porcine large animal study to evaluate usability, performance, and vessel response.

PERFORMANCE DATA - LEVERAGED

The following performance data was leveraged from the predicate IMPEDE device, due to similarities between the devices.

Biocompatibility testing

The biocompatibility evaluation for the IMPEDE device was conducted in accordance with ISO10993-1 Biological Evaluation of Medical Devices – Part 1: Guidance on Selection of Tests. The implant is considered a permanent implant, blood contacting device, and the introducer is considered an external communicating device, limited (<24hour) circulating blood contacting device.

The battery of testing for the implant portion of the device included the following tests:

- Cytotoxicity
- Sensitization
- Irritation
- Genotoxicity
- Hemocompatibility
- Intramuscular Implantation
- Materials Mediated Pyrogenicity
- Systemic toxicity
- Subchronic toxicity
- Chronic toxicity

The battery of testing for the Introducer Sheath included the following tests:

- Cytotoxicity
- Sensitization
- Irritation
- Hemocompatibility
- Materials Mediated Pyrogenicity
- Systemic toxicity

Mechanical, Visual and Characterization testing

- Radiopacity
- Particulate Testing
- MRI Compatibility
- Packaging/Sterilization
- Material Characterization

Animal Study

The IMPEDE Embolization Plug was evaluated in a number of animal studies including multiple animal species and implantation sites. This analysis included the following studies:

- 30, 60, and 90-day porcine large animal study
- 90 day standard subcutaneous rat study
- 90 and 180-day custom (foam only) subcutaneous rat study
- 4, 13, and 26-week intramuscular implant rabbit study

BASIS FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The IMPEDE-FX Embolization Plug shares technology and functionality with the predicate IMPEDE Embolization Plug (K181051) and reference Gel-Block Embolization Pledgets (K113266) as all are embolic devices that are intended to obstruct blood flow in the vasculature. The subject, predicate, and reference devices are delivered in a compressed shape to allow delivery through a catheter and each expands in a similar fashion once deployed to facilitate occlusion. Each are similar in geometry and consist of degradable materials of construction. While the specific device materials for the subject and Gel-Block predicate devices are not identical, the subject and IMPEDE Embolization Plug predicate devices share many of the same materials. The primary difference between the subject IMPEDE-FX and predicate IMPEDE devices is the lack of the anchor coil in the subject device design. The reference Gel Block Embolization Pledgets (K113266) device, similar to the subject device, lacks a separate anchoring mechanism. Since the migration resistance of the subject device without the anchor coil may be different as compared to the predicate IMPEDE device, it has been indicated for use as an accessory or adjunct to the IMPEDE device.

Test results demonstrated that all acceptance criteria were met; therefore, the device conforms to established product specifications and intended use. Based upon the same intended use and principle of operation, technology, and nonclinical testing it is concluded that the IMPEDE-FX Embolization Plug is substantially equivalent to the predicate device.