June 22, 2018

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

Re: K181051
Trade/Device Name: IMPEDE Embolization Plug
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular Embolization Device
Regulatory Class: Class II
Product Code: KRD
Dated: April 17, 2018
Received: April 20, 2018

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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,

Brian D. Pullin -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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)*
K181051

Device Name
IMPEDE Embolization Plug

Indications for Use *(Describe)*
The IMPEDE Embolization Plug is indicated 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.

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510(K) SUMMARY

SUBMITTER

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

Phone: 408-649-5175 x 711
Fax: 669-230-5932

Contact Person: Meghan Reu, Quality and Regulatory Manager
Date Prepared: June 19, 2018

DEVICE

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

PREDICATE DEVICES

Vascular Solutions Gel-Block Embolization Pledgets (K113266)
Reverse Medical Micro Vascular Plug System (K150108)
Biomerix Vascular Occlusion Device and Loader (K043371)
Amplatzer Vascular Plug 4 (K113658)

DEVICE DESCRIPTION

The IMPEDE Embolization Plug is indicated to obstruct or reduce the rate of blood flow in the peripheral vasculature. The IMPEDE Embolization Plug consists primarily of two components:

- IMPEDE Embolization Plug
- IMPEDE Introducer Sheath

The IMPEDE Embolization Plug is a permanent implant, blood contacting pushable embolization device comprised of a self-expanding porous, degradable polyurethane-based foam plug, a distal pre-shaped helical platinum-iridium alloy anchor coil, an etched passivated superelastic nitinol core wire, and a proximal platinum-iridium alloy marker band.

The IMPEDE polyurethane foam undergoes slow 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 in the IMPEDE Introducer Sheath which is made of a PEEK tube and a polycarbonate luer hub. The implant is categorized as a permanent implant, blood contacting device, and the introducer is categorized as an external communicating device, limited (<24hour) circulating blood contacting device. The assembled unit is supplied e-beam sterile for single use.

The device is delivered with the plug in the crimped state to the target vessel using a guidewire through a standard angiographic catheter. Upon deployment in the target vessel and exposure to an aqueous environment and body temperature, the plug will self-expand to embolize the target vessel. The anchor coil stabilizes the device within the vessel to allow precise control of placement and to minimize risk of device migration and unintended thromboembolism while the plug expands to embolize and conform to the vessel lumen.

INDICATIONS FOR USE

The IMPEDE Embolization Plug is indicated to obstruct or reduce the rate of blood flow in the peripheral vasculature.

COMPARSON OF TECHNOLOGICAL CHARACTERSTICS WITH THE PREDICATE DEVICES

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 devices:

TABLE 1: PREDICATE DEVICE COMPARISON CHART

	IMPEDE Embolization Plug	**Reverse Medical Micro Vascular Plug System**	**Biomerix Vascular Occlusion Device and Loader**	**Amplatzer Vascular Plug 4**	**Vascular Solutions Gel-Block Embolization Pledgets**
510(k) Number	K181051	K150108	K043371	K113658	K113266
Intended Use	The IMPEDE® Embolization Plug is indicated to obstruct or reduce the rate of blood flow in the peripheral vasculature	The Reverse Medical Corporation MVP Micro Vascular Plug System is indicated to obstruct or reduce the rate of blood flow in the peripheral vasculature	The Biomerix Vascular Occlusion Device is intended for arterial and venous embolization in the peripheral vasculature	The AMPLATZER ™ Vascular Plug 4 is indicated for arterial and venous embolizations in the peripheral vasculature	Gel-Block embolization pledgets are intended for use in embolization of hypervascular tumors and arteriovenous malformations (AVMs).

	IMPEDE Embolization Plug	**Reverse Medical Micro Vascular Plug System**	**Biomerix Vascular Occlusion Device and Loader**	**Amplatzer Vascular Plug 4**	**Vascular Solutions Gel-Block Embolization Pledgets**
Implant Dimensions	OD(mm) x L(mm) IMP-05: 6 x 10 IMP-07: 8 x 10 IMP-12: 12 x 15	OD(mm) x L(mm) MVP-3: 5.3 x 12 MVP-5: 6.5 x 12 MVP-7: 9.2 x 16 MVP-9: 13 x 18	OD(mm) x L(mm) 4 x 15 6 x 15 8 x 15	OD(mm) x L(mm) 4 x 7 6 x 7 8 x 7 10 x 7 12 x 8 14 x 8 16 x 8	OD(mm) x L(cm) 5 x 0.5 3 x 0.5 3 x 0.25
Vessel Indication	2-10mm (3 models)	1.5 – 9mm (4 models)	4-16mm	2-20mm (Various models)	Not stated in the IFU
Application / Product Code	21 CFR 870.330 (KRD)	21 CFR 870.330 (KRD)	21 CFR 870.330 (KRD)	21 CFR 870.330 (KRD)	21 CFR 870.330 (KRD)
Classification	Class II	Class II	Class II	Class II	Class II
Delivery/Deployment Method	Pushable via 4F-6F catheter through introducer to target vessel by guidewire	Delivery wire through a .021” - .043” ID microcatheter	Commercial 5F-7F Catheters, advanced via obturator	Via 4F-7F catheter through the Loader to target vessel by Delivery Wire	Via .021” - .038” ID catheter
How transferred to catheter	Pre-loaded in Peek Introducer Sheath with polycarbonate luer hub; transferred to catheter by advancing guidewire	Through an access sheath	Compressed into Loader and transferred to Catheter by pushing with guidewire.	Pre-loaded in Loader	Stored individually in a transparent delivery tube with a luer lock on the flushing end and a vented cap on the delivery end. One syringeis included for delivery of the pledgets.
Detachment	No Pushable	Yes Mechanical	No Pushable	Yes Mechanical	No Injectable
Implant Materials	Polyurethane (polymer foam), Nitinol Core Wire, Pt/Ir Coil, Pt/Ir markerband, Adhesive	Nitinol, platinum, ePTFE	Polyurethane (polymer foam)	Nitinol, platinum, stainless steel	Porcine Gelatin
Anchoring Mechanism	Pt/Ir and Nitinol Anchor Coil	Nitinol Basket	Polymer Foam	Nitinol Basket	N/A
Biocompatibility	Meets requirements of ISO 10993-1	Meets requirements of ISO 10993-1	Meets requirements of ISO 10993-1	Meets requirements of ISO 10993-1	Meets requirements of ISO 10993-1
How Provided	Sterile, single-use, pre-loaded in introducer	Sterile, single-use	Sterile, single-use	Sterile, single-use	Sterile, single-use, pre-loaded in delivery tube

	IMPEDE Embolization Plug	Reverse Medical Micro Vascular Plug System	Biomerix Vascular Occlusion Device and Loader	Amplatzer Vascular Plug 4	Vascular Solutions Gel-Block Embolization Pledgets
Sterilization Method	E-Beam	EO	Gamma	EO	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	No	No	No	Yes – Significant degradation by the 12 week time point
Radiopacity	Distal Pt/Ir coil and proximal Pt/Ir Marker Band band	Proximal and Distal Marker Bands	Through the use of contrast media filled obturator	Proximal and Distal Marker Bands	50% contrast with 50% saline mixture
Accessories	Introducer	Torquer	Loader	Loader	Injection syringe

PERFORMANCE DATA

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

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 Material Characterization testing

Bench testing conducted for the IMPEDE device included the following:

- Simulated use testing
  - Accessory Compatibility (Guidewire, Catheter and Introducer)
  - Delivery Performance (Working Time, Deliverability, Migration)
  - Implantation Performance (Plug Expansion, Migration, Bond Integrity)
- Extractables and Leachables Toxicological Analysis
- Degradation Products Toxicological Analysis
- In-Vitro Degradation Rate Analysis
- Radiopacity
- Radial Force
- Particulate Testing
- MRI Compatibility
- Packaging/Sterilization
- Material Characterization
- Corrosion Testing
- Dimensional Inspection
- Visual Inspection

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

CONCLUSION

The IMPEDE Embolization Plug is substantially equivalent to the identified predicates in regards to performance, intended use, design, materials, principle of operation and overall technological characteristics. The nonclinical data support the substantial equivalence of the subject device and the verification and validation testing demonstrate that the subject device should perform as intended when used as instructed in the instructions for use.