



June 18, 2019

Biosphere Medical, S.A.
Alix Fonlladosa
Regulatory Affairs Manager
Parc des Nations – Paris Nord 2, 383 rue de la Belle Etoile
Roissy en France, 95700 Fr

Re: K183578

Trade/Device Name: Torpedo Gelatin Foam
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular embolization device
Regulatory Class: Class II
Product Code: KRD
Dated: May 20, 2019
Received: May 21, 2019

Dear Alix Fonlladosa:

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

Indications for Use

510(k) Number (if known)

K183578

Device Name

Torpedo Gelatin Foam

Indications for Use (Describe)

Intended Use: Torpedo Gelatin Foam is indicated for use in embolization of hypervascular tumors

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.

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510(k) Summary
K183578

June 12, 2019

General Provisions	Submitter Name:	Biosphere Medical, S.A.
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	Telephone Number:	+33 (0)1 48 17 25 25
	Fax Number:	+33 (0)1 49 38 02 68
	Contact Person:	Rosène Amossé
	Registration Number:	9615728

Subject Device	Trade Name:	Torpedo Gelatin Foam
	Common/Usual Name:	Embolization device
	Classification Name:	21 CFR § <u>870.3300</u> Vascular Embolization Device

Predicate Device	Trade Name:	EmboCube Embolization Gelatin
	Classification Name:	21 CFR § <u>870.3300</u> Vascular Embolization Device
	Premarket Notification:	K181021
	Manufacturer:	Biosphere Medical, S.A.

Classification	Class II
	21 CFR § <u>870.3300</u>
	FDA Product Code: KRD
	Review Panel: Division of Cardiovascular Devices

Intended Use	Torpedo Gelatin Foam is indicated for use in embolization of hypervascular tumors.
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Torpedo Gelatin Foam is a hydrophilic medical device which consists of resorbable dry gelatin foam that is compressed into a cylindrical shape and preloaded into a cartridge with a standard female and male luer fittings. The device is available in two sizes (0.9 mm and 1.7 mm) and two lengths configurations (10 mm and 20 mm).

Device Description	Reference code	Compressed / Dehydrated Torpedo Diameter	Uncompressed / Hydrated Torpedo Section	Torpedo Length
		TOR2510	0.9 mm	2.5 mm x 2.5 mm
	TOR2520	0.9 mm	2.5 mm x 2.5 mm	20 mm
	TOR5010	1.7 mm	5.0 mm x 5.0 mm	10 mm
	TOR5020	1.7 mm	5.0 mm x 5.0 mm	20 mm

Once rehydrated, the deformable torpedoes can be injected into the target vessel with an intravascular catheter or a micro-catheter (depending on the size range) to provide a mechanical barrier to blood flow. Contrast enhancement may be used to monitor the embolization procedure using fluoroscopy. The device is intended for single use and is provided sterile.

Comparison to Predicate

Torpedo Gelatin Foam is similar in design to the predicate device, EmboCube Embolization Gelatin (K181021), as both of them provide a mechanical barrier to blood flow in the vasculature and are delivered using catheters. The changes to the device are as follows: a) A variant of the gelatin cube device has been added to the range, b) A new packaging has been added, c) A blunt stylet has been included.

The subject device is available in two sizes, as the predicate device. The subject and predicate devices differ in shape. The predicate EmboCube Embolization Gelatin (K181021) has a cubic shape, whether dry or hydrated. At the dry state, the subject Torpedo Gelatin Foam is compressed into a cylindrical shape. In the uncompressed / hydrated state, the subject Torpedo Gelatin Foam is a solid rectangle of the same section as the predicate (2.5 mm or 5.0 mm), only the length differs. Both the subject device and the predicate device, EmboCube Embolization Gelatin, K181021 are made wholly from the identical resorbable porcine gelatin.

The technological differences between the subject and predicate devices have been evaluated through biocompatibility, bench and animal testing to provide evidence of substantial equivalence of the Torpedo Gelatin Foam to the predicate device, EmboCube Embolization Gelatin (K181021).

Safety & Performance Tests

No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for these devices. However, vascular embolization devices are subject to the special controls specified in "*Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document: Vascular and Neurovascular Embolization Devices*", issued on December 29, 2004. In addition, the subject device follows the FDA Draft Guidance on Medical Devices Containing Materials Derived from Animal Sources (Except for In Vitro Diagnostic Devices), issued on January 23, 2014.

A battery of tests performed on Torpedo Gelatin Foam were designed to demonstrate that the device meets critical design specifications as well as clinical performance attributes for its intended use. Where appropriate, the tests were based on the requirements of the following documents:

- FDA Guidance Class II Special Controls Guidance Document: Vascular and Neurovascular Embolization Devices (December 29, 2004)
 - ASTM F2096-11, *Standard Test Method for Detecting Gross Leaks in Medical Packaging by Internal Pressurization (Bubble Test)*
 - ASTM F1140/F1140M-13, *Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages for Medical Applications*
 - ASTM F88/F88M-15, *Standard Test Method for Seal Strength of Flexible Barrier Materials*
 - ASTM D4332-14, *Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing*
 - ASTM D4169-16, *Standard Practice for Performance Testing of Shipping Containers and Systems*
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- ASTM F1980-16, *Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices*
 - NF EN ISO 11137-1:2016, *Sterilization of health care products -- Radiation -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*
 - NF EN ISO 10993-1:2010, *Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process*, and the FDA Modified ISO 10993 Test Profile FDA Memo G95-1.
 - NF EN ISO 11607-1:2018, *Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems*
 - ISO 7864:2016, *Sterile hypodermic needles for single use -- Requirements and test methods*
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Torpedo Gelatin Foam was evaluated for various performance attributes to demonstrate the substantial equivalence of the device to the predicate. The following is a list of all testing that was successfully completed:

- Macroscopic appearance (visual inspection)
- Compressed (dry) torpedo size
- Maximum swelling (hydrated size)
- Humidity (H₂O analysis)
- Sterility
- Pyrogenicity (Bacterial endotoxins)
- Deliverability with a stylet
- Deliverability with catheters and radiopaque contrast agents
- Flush test carried out on aged and sterilized subject devices
- Resorption
- Embolic effect
- Comparative FTIR analysis for any foreign material transfer

**Safety &
Performance
Tests**
(continued)

Biocompatibility testing was adopted from the predicate device EmboCube Embolization Gelatin, K181021. The only difference between the subject device and the legally marketed predicate device is that the subject device will be crimped and shaped into a torpedo. FTIR spectroscopy was performed in order to verify that there is no transfer of material from the crimper to the subject device. No further biocompatibility testing was required to qualify the subject device.

An animal study was conducted on seven test (Torpedo Gelatin Foam) and eight control (EmboCube Embolization Gelatin, K181021) adult female sheep in the renal arteries over a period of 4 weeks. The animal study evaluated vascular safety, local tissue effects, and in vivo degradation of the Torpedo Gelatin Foam. Angiography and/or histopathology confirmed that the Torpedo Gelatin Foam provided an embolic effect in renal arteries for at least four weeks. Normal flow of the renal arterial vasculature was never recovered in any animal at any time point. There was no significant difference for artery patency between any articles at any time point. All test animals had a necrotized renal tissue, indicative of successful embolization. The animals were clinically normal throughout the study duration.

The difference between the modified device and the cleared device, Biosphere EmboCube Embolization Gelatin [K181021] has raised no new issues.

**Summary of
Substantial
Equivalence**

Based on the indications for use, design, safety and performance testing, the subject Torpedo Gelatin Foam is substantially equivalent to the predicate device, the currently marketed EmboCube Embolization Gelatin, manufactured by Biosphere Medical, 510(k) K181021.
