November 21, 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: K192480
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: August 30, 2019
Received: September 10, 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, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192480

Device Name
Torpedo Gelatin Foam

Indications for Use *(Describe)*
Torpedo Gelatin Foam is indicated for use in embolization of:
• Hypervascular tumors
• Blood vessels to occlude blood flow to control bleeding / hemorrhaging 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 K192480

November 18, 2019

General Provisions	Submitter Name:	Biosphere Medical, S.A.
	Address:	Parc des Nations – Paris Nord 2 383, rue de la Belle Etoile 95700 Roissy-en-France, France
	Telephone Number:	+33 (0)1 48 17 25 29
	Fax Number:	+33 (0)1 49 38 02 68
	Contact Person:	Alix Fonlladosa
	Registration Number:	9615728
Subject Device	Trade Name:	Torpedo Gelatin Foam
	Common/Usual Name:	Embolization device
	Classification Name:	21 CFR § 870.3300 Vascular Embolization Device
Predicate Device	Trade Name:	EmboCube Embolization Gelatin
	Classification Name:	21 CFR § 870.3300 Vascular Embolization Device
	Premarket Notification:	K183120
	Manufacturer:	Biosphere Medical, S.A.
Reference Device #1	Trade Name:	Torpedo Gelatin Foam
	Classification Name:	21 CFR § 870.3300 Vascular Embolization Device
	Premarket Notification:	K183578
	Manufacturer:	Biosphere Medical, S.A.
Classification	Class II 21 CFR § 870.3300 FDA Product Code: KRD Division of Cardiovascular Devices	
Intended Use	Torpedo Gelatin Foam is indicated for use in embolization of: • Hypervascular tumors • **Blood vessels to occlude blood flow to control bleeding / hemorrhaging in the peripheral vasculature**	

Device Description

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).

Reference code	Compressed / Dehydrated Torpedo Diameter	Uncompressed / Hydrated Torpedo Section	Torpedo Length
TOR2510	0.9 mm	2.5 mm x 2.5 mm	10 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.

Torpedo Gelatin Foam is similar in design to the predicate device, EmboCube Embolization Gelatin (K183120), 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.

Comparison to Predicate

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 (K183120) 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 (K183120) are made wholly from the identical resorbable porcine gelatin.

The bench testing was leveraged from the cleared Torpedo Gelatin Foam (K183578), because no changes to material, general design or processing were made.

The previous animal testing listed in the 510(k) of the predicate device EmboCube Embolization Gelatin (K183120) was leveraged to support the new Indications for Use of the subject device Torpedo Gelatin Foam.

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.

Safety & Performance Tests

Substantial equivalence between the reference device and the predicate device was supported by the animal testing listed in the 510(k) of the reference device Torpedo Gelatin Foam (K183578). An animal study was conducted on seven test (Torpedo Gelatin Foam, K183578) and eight control (EmboCube Embolization Gelatin, K183120) adult female sheep in the renal arteries over a period of 4 weeks. Comparison of safety and performances between both devices was assessed by comparing the vascular occlusion, local tissue effects, and in vivo degradation. Angiography and histopathology confirmed that the Torpedo 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.

Device design of the subject device was leveraged from the reference device Torpedo Gelatin Foam (K183578). Both products have exactly the same materials, design and processing. There are no differences that could raise new questions of safety and effectiveness for the use of the subject device, Torpedo Gelatin Foam, in bleeding / hemorrhaging application.

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) K183120.