February 14, 2020

Embolic Acceleration, LLC (EMBA)
Veronica McDougall
Quality Director
3451 Commerce Pkwy
Miramar, Florida 33025

Re: K200083
Trade/Device Name: EMBA Hourglass® Peripheral Embolization Device (PED)
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular Embolization Device
Regulatory Class: Class II
Product Code: KRD
Dated: January 10, 2020
Received: January 15, 2020

Dear Veronica McDougall:

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,

for

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)*
K200083

Device Name
EMBA Hourglass® Peripheral Embolization Device (PED)

Indications for Use *(Describe)*
The EMBA Hourglass® Peripheral Embolization Device (PED) is indicated to obstruct or reduce the rate of blood flow in the peripheral vasculature in 6-8mm blood vessels. The device is not indicated for use in blood vessels subject to repetitive motion, such as extremity or pulmonary vessels.

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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EMBA Hourglass® Peripheral Embolization Device
510(k) Summary
21 CFR 807.92

In accordance with 21 CFR 807.92, a 510(k) Summary upon which substantial equivalence determination is based shall include the following:

Submitter Information

Applicant:	Embolic Acceleration, LLC (EMBA) 3451 Commerce Parkway Miramar, FL 33025
Phone:	954-874-1016
Contact:	Veronica McDougall, Quality Director
Date Prepared:	January 10, 2020

Subject Device Information

Trade Name:	EMBA Hourglass® Peripheral Embolization Device
Common Name:	Vascular device for promoting embolization
Classification Name:	Vascular embolization device
Predicate Device:	EMBA Hourglass™ Peripheral Embolization Device (K171845)
510(k) Number:	K200083
Product Code:	KRD
Device Class:	Class II
Regulation Number:	21 CFR 870.3300
Regulatory Panel:	Cardiovascular

Device Description

The Hourglass® Peripheral Embolization Device (PED) consists of a covered, implantable, self-expanding hourglass-shaped structure (Embolic Device) preloaded in a catheter-based Delivery System. The Embolic Device is intended to be deployed to the

target site in the vasculature under fluoroscopic guidance. The product is shipped sterile and labeled for single use only.

Indications for Use

The EMBA Hourglass® Peripheral Embolization Device (PED) is indicated to obstruct or reduce the rate of blood flow in the peripheral vasculature in 6-8mm blood vessels. The device is not indicated for use in blood vessels subject to repetitive motion, such as extremity or pulmonary vessels.

Comparison of Technological Characteristics to Predicate Device

The fundamental technological characteristics of the subject device are identical to those of the predicate device with the exception of the length of the Delivery System. The Delivery System length of the subject device is 80cm, while the Delivery System length of the predicate device is 120cm. All other design and material characteristics are identical.

Performance Testing

A risk analysis of the device modifications was completed. An engineering assessment concluded that no new risks or modified existing risks were introduced. Therefore, the bench, animal, and clinical testing performed for the predicate device are adequate for evaluating the performance of the subject device. In addition, the subject device is manufactured using the same materials and manufacturing processes as the predicate device, so biocompatibility testing in accordance with ISO 10993-1 performed for and passed by the predicate device applies to the subject device. No additional testing is required to demonstrate biocompatibility of the subject device.

Conclusions

Review of the subject device’s indications for use and technological characteristics in comparison to those of the predicate device show that the subject device, the EMBA Hourglass® Peripheral Embolization Device, is substantially equivalent to the predicate device.