



July 1, 2022

Obsidio, Inc.
% Janice Hogan
Partner
Hogan Lovells US LLP
1735 Market Street, Suite 2320
Philadelphia, Pennsylvania 19103

Re: K213385
Trade/Device Name: GEM
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular Embolization Device
Regulatory Class: Class II
Product Code: KRD
Dated: June 8, 2022
Received: June 8, 2022

Dear Janice Hogan:

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

Indications for Use

510(k) Number (if known)

K213385

Device Name

GEM™

Indications for Use (Describe)

Obsidio GEM™ is indicated for use in the embolization of:

- Hypervascular tumors,
- Blood vessels to occlude blood flow for controlling 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"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
Obsidio GEM™**

Obsidio, Inc. Address, Telephone Number, Contact Person and Date Prepared

Obsidio, Inc.

1520 Main Street, Unit 4-C
Columbia, SC 29201

Phone: (267)-235-5951
Contact Person: Ehsan Jabbarzadeh
Date Prepared: June 3, 2022

Name of Device and Name/Address of Sponsor

GEM™

Common or Usual Name

Vascular Embolization Device

Classification Name

Device, Vascular, For Promoting Embolization

Predicate Devices

Biosphere Medical, S.A. EmboCube™ Embolization Gelatin (K183120)

Intended Use / Indications for Use

Obsidio GEM™ is indicated for use in the embolization of:

- Hypervascular tumors
- Blood vessels to occlude blood flow for controlling bleeding/hemorrhaging in the peripheral vasculature

Technological Characteristics

GEM™ consists of a pre-hydrated bioresorbable gelatin, layered silicate (Laponite) mixture, and tantalum powder packaged in a 1 ml syringe with a standard luer lock tip. The device is provided ready to use. The device is injected into a target vessel through intravascular catheters to provide a mechanical barrier to blood flow. The device is intended for single use and is provided sterile.

Performance Data

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.

GEM™ was evaluated for various performance attributes to demonstrate the substantial equivalence of the device to the predicate. Non-clinical performance testing included:

- Macroscopic Inspection (Visual Inspection)
- Component Characterization
- Mechanical Property (Rheometry)
- pH test
- Injection Force
- Catheter Deliverability
- Component Sterilization Validations
- Aseptic Fill Validations (ISO 13408-1:2008)
- Packaging Validations (Shelf-life, Transit, Sealing)
- Sterility (ANSI/AAMI/ISO 11737-2:2019)
- Pyrogenicity (ANSI/AAMI ST72:2019)
- Biocompatibility (ISO 10993-1:2018)
 - Cytotoxicity
 - Sensitization
 - Irritation
 - Material Mediated Pyrogenicity
 - Hemolysis
 - Complement Activation
 - Chemical Characterization/Toxicological Risk Assessment

Two animal studies were conducted; one for hypervascular tumors and a second for the indication to use in blood vessels to occlude blood flow to control bleeding/hemorrhaging in the peripheral vasculature.

The first animal study was conducted on ten test (GEM™) and nine control (EmboCube™ Embolization Gelatin, K183120) adult swine (evenly distributed male and female) in 38 renal arteries and 19 hepatic arteries over 4 timepoints (4 days, 30 days, 90 days, 180 days) to address the indication for embolization of hypervascular tumors. The animal study evaluated overall in life health, test article performance, occlusion, arterial flow scale, and regional and downstream response to GEM™ along with an analysis of explanted tissues to evaluate for downstream layered silicate presence/toxicity.

The second animal study for simulated hemorrhage was conducted on five test (GEM™) and five control (EmboCube™ Embolization Gelatin, K183120) adult swine in eight renal arteries and eight splenic arteries over a period of 7 days for the evaluation of persistence of hemostasis. The animal study included prespecified endpoints for overall in life health, test article performance, hemostatic success, macroscopic regional tissue response, time to hemostasis, and embolization effectiveness of GEM™. The product met its specifications. All test results confirmed that the technological differences between the subject and the predicate device did not adversely impact its performance.

Substantial Equivalence

GEM™ has the same intended uses, indications for use, similar technological characteristics, and principle of operation as its predicate device. The technological differences involving composition and preparation between GEM™, and its predicate device, raise no new issues of safety or effectiveness. Performance data demonstrate that GEM™ is substantially equivalent to the predicate EmboCube™ Embolization Gelatin.

Conclusions

Based on the indications for use, design, safety, and performance testing, GEM™ is substantially equivalent to the predicate device, EmboCube™ Embolization Gelatin.