April 10, 2026

Okami Medical, Inc.
Cora Sim
Sr. Manager, RA/QA
8 Argonaut, Suite 100
Aliso Viejo, California 92656

Re: K260508
Trade/Device Name: LOBO Vascular Occlusion System
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular Embolization Device
Regulatory Class: Class II
Product Code: KRD
Dated: February 13, 2026
Received: February 17, 2026

Dear Cora Sim:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 L. MALONE -S

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260508

Device Name
LOBO Vascular Occlusion System

Indications for Use *(Describe)*
The Okami Medical LOBO Vascular Occlusion System is intended for use to obstruct or reduce the rate of blood flow in arteries of the peripheral vasculature. The device is not indicated for use in blood vessels where crush or bend forces are anticipated (e.g. joint areas, superficial 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.

LOBO Vascular Occlusion System

510(k) SUMMARY

Sponsor	Okami Medical, Inc. 8 Argonaut, Suite 100 Aliso Viejo, CA 92656 USA
Contact	Cora Sim 949-446-9710 coras@okamimedical.com
Device Trade Name	LOBO Vascular Occlusion System
Common Name	Vascular embolization device
Classification Name	Device, vascular, for promoting embolization
Device Class	Class II
Regulation Number	870.3300
Product Code	KRD
Predicate Device	K192083 – LOBO Vascular Occlusion System – Product Code KRD
Reference Device	K220383 – LOBO Vascular Occlusion System – Product Code KRD
510 (k) Summary Date	March 13, 2026

Device Description Summary

The LOBO Vascular Occlusion System (Model LOBO-3-LP) is a line extension of the LOBO family of vascular occluders which includes the predicate LOBO Vascular Occlusion System (K192083).

The Okami Medical LOBO Vascular Occlusion System is a single-use, sterile medical device system designed to occlude arteries of the peripheral vasculature. The LOBO system consists of an implant connected to the distal end of a pusher (the "device") and a handpiece, each packaged separately. The implant consists of a braided, self-expanding, 2-disk, nitinol wireform with radiopaque markers positioned on both ends to aid with fluoroscopic visualization. The device is placed through commercially available delivery catheters to the intended treatment site.

Intended Use / Indications for Use

The Okami Medical LOBO Vascular Occlusion System is intended for use to obstruct or reduce the rate of blood flow in arteries of the peripheral vasculature. The device is not indicated for use in blood vessels where crush or bend forces are anticipated (e.g. joint areas, superficial vasculature).

Indications for Use Comparison

The indications for use statement between the primary predicate and the subject device is identical.

Comparison of Technological Characteristics

The subject Okami Medical LOBO Vascular Occlusion System has the same or similar technological characteristics when compared to the primary and reference predicates (e.g. intended use, principle of operation, fundamental design characteristics, materials, etc.).

All devices share the same intended use and principle of operation, namely as a self-expanding nitinol mesh device delivered to the desired embolization site through a delivery catheter by means of a wire and, upon release, the device expands to reduce flow in the vessel or desired embolization site.

Each of the fundamental design characteristics of the Okami Medical Vascular Occlusion System are also present in the primary predicate or reference predicate. Any minor design differences between the primary predicate device and the subject device are covered by the reference predicate.

Non-clinical Performance Verification Testing

Performance verification testing was conducted for the subject LOBO Vascular Occlusion System to demonstrate the suitability of the device for its intended use. The results of the testing indicate that the LOBO Vascular Occlusion System is substantially equivalent to the predicate device.

Performance testing included:

- Dimensional/Visual Inspection
- Implant Chronic Outward Force Testing
- Simulated Use Testing
- Deployment and Retraction Force Testing
- Compatibility Testing
- Torque to Failure Testing
- Hemostasis Testing
- Implant Detachment Testing
- System Tensile Strength Testing
- Pusher Kink Testing
- Adapter Tube Tensile Strength Testing
- Adapter Tube Buckle Resistance Testing
- GLP Animal Study

A GLP animal study was conducted to evaluate the acute safety, performance, and handling of the LOBO-3-LP device as compared to a commercially available predicate device. The device was successfully delivered and deployed in the target vessels and reduction of blood flow was achieved as intended, with no device-related migration or vessel damage observed. The results of the study support the safe and effective performance of the LOBO-3-LP device for its intended use.

No clinical studies were required.

Conclusions

The LOBO Vascular Occlusion System is substantially equivalent to the predicate in terms of intended use, principle of operation, technological characteristics, and performance characteristics. Nonclinical performance verification testing, which included bench and animal testing, was performed to demonstrate that the subject LOBO Vascular Occlusion System is substantially equivalent to the predicate device.