March 8, 2024

Okami Medical, Inc.
Jill Delsman
Official Applicant
8 Argonaut, Suite 100
Aliso Viejo, California 92656

Re: K240384
Trade/Device Name: SENDERO Microcatheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: February 6, 2024
Received: February 8, 2024

Dear Jill Delsman:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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.

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,

Samuel G. Raben -S

Lydia Glaw
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.

Submission Number *(if known)*

K230384

Device Name

SENDERO Microcatheter

Indications for Use *(Describe)*

The SENDERO Microcatheter is intended for the peripheral vasculature for the infusion of diagnostic and therapeutic agents.

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
PRAStaff@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

Sponsor	Okami Medical, Inc. 8 Argonaut, Suite 100 Aliso Viejo, CA 92656 USA
Contact	Jill Delsman 949-446-9710 jilld@okamimedical.com
Device Trade Name	SENDERO Microcatheter
Common Name	Microcatheter
Classification Name	Catheter, Percutaneous
Regulation Number	870.1250
Product Code	DQY
Predicate Device	K231600 – SENDERO Microcatheter – Product Code DQY
510 (k) Summary Date	March 1, 2024

Device Description Summary

The SENDERO Microcatheter is a single lumen, variable stiffness catheter with a radiopaque marker on the distal end and a Luer-lock hub on the proximal end. A hydrophilic coating on the catheter shaft reduces friction during navigation through the vasculature. The device is delivered to the target location using standard interventional techniques (e.g. use of guidewire, guide catheter, etc.) under fluoroscopic guidance. Once at the target location, the lumen of the device allows for the introduction of diagnostic and therapeutic agents into the peripheral vasculature.

Intended Use / Indications for Use

The SENDERO Microcatheter is intended for the peripheral vasculature for the infusion of diagnostic and therapeutic agents.

Indications for Use Comparison

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

Comparison of Technological Characteristics

The modified SENDERO Microcatheter is substantially equivalent to the predicate device with respect to intended use, principle of operation, and fundamental design characteristics.

Only minor modifications have been made to the SENDERO Microcatheter materials and construction including a change in polyamide material specification, design enhancement of the catheter braid, increase in opacity of the marker band, increase in minimum catheter inside dimension and an update to the Luer-lock hub for compliance with ISO 80369-7 requirements, as well as labeling updates for maximum pressure specification.

The minor differences between the predicate and the subject device do not raise new or different questions of safety and effectiveness in comparison to the predicate device. These modifications have been addressed through design control activities, including a risk assessment to determine the verification and validation activities required to demonstrate the acceptability and substantial equivalence of any minor differences in technological characteristics between the predicate and subject device. Results of the verification and validation activities met the predefined acceptance criteria, demonstrating the subject device is substantially equivalent in terms of intended use, principle of operation, technological characteristics, and performance characteristics to the SENDERO Microcatheter cleared under K231600.

Non-clinical Performance Testing

A risk analysis based on the principles of ISO 14971 was performed to assess the impact of the modifications to the SENDERO Microcatheter. Performance testing, as outlined below, was conducted to demonstrate the subject device met the same performance criteria established for the predicate device. The results of the testing indicate that the modified SENDERO Microcatheter is substantially equivalent to the predicate device.

Performance testing included:

- Dimensional/Visual Inspection
- Coating Thickness and Lubricity
- Simulated Use Testing
- Catheter Coating Integrity
- Compatibility Testing
- Burst Pressure Testing (per ISO 10555-1)
- Catheter Tensile Strength (per ISO 10555-1)
- Catheter Tip Strength
- Kink Diameter Testing
- Torque Testing
- Hub Testing (per ISO 80369-7)
- Flowrate Testing (per ISO 10555-1)
- Radiopacity Testing (per ASTM F640)
- Particulate Testing
- Biocompatibility Testing (per ISO 10993-1)
    - Cytotoxicity
    - Sensitization

- Irritation
- Acute Systemic Toxicity
- Material-Mediated Pyrogenicity
- Hemocompatibility

No clinical studies were required.

Conclusions

The modified SENDERO Microcatheter is substantially equivalent to the predicate device in terms of intended use, principle of operation, technological characteristics, and performance characteristics.