February 8, 2024

Reflow Medical, Inc.
Lori Grace
Sr. Director Regulatory Affairs
208 Avenida Fabricante #100
San Clemente, California 92672

Re: K233350
Trade/Device Name: SINC Support Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: January 12, 2024
Received: January 12, 2024

Dear Lori Grace:

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

for 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K233350

Device Name
SINC Support Catheter

Indications for Use *(Describe)*
SINC Support Catheters are intended to be used in conjunction with steerable guidewires to access discrete regions of the peripheral vasculature. They may be used to facilitate placement and exchange of guidewires and other interventional devices, and provide a conduit for delivery of saline solutions or diagnostic/ therapeutics 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.

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208 Avenida Fabricante, Suite 100
San Clemente, CA 92672

510(k) Summary (21 CFR 807.92)

The following 510(k) Summary is submitted in accordance with the requirements of 21 CFR 807.92:

510(k) Summary:	**K233350**
Sponsor/Submitter:	ReFlow Medical, Inc. 208 Avenida Fabricante, Suite 100 San Clemente, CA 92672
Contact Person:	Ms. Lori Grace Sr. Director, Regulatory Affairs lgrace@reflowmedical.com 612-749-6031
Date Prepared:	January 25, 2024
Device Trade Name(s):	SINC™ Support Catheter
Common Name:	Percutaneous Catheter
Device Classification:	Class II
Regulation Number:	21 CFR 870.1250
Classification Name:	Catheter, Percutaneous
Product Code:	DQY
Primary Predicate Device: NAME	spex LP
Secondary Predicate Device: NAME	Not applicable

Device Description

The SINC™ (Selective Interventional Navigation Catheter) Support Catheters are single lumen catheters designed to access peripheral vasculature. These catheters are available in a variety of lengths and offer a side port. Each configuration has a braided support matrix and hydrophilic coating on the distal segment of the catheter. The distal tip is clearly distinguished by a radiopaque gold coated tip.
The SINC Support Catheters will also allow for exchange of guidewires and other interventional devices and provide a conduit for delivery of saline solutions or diagnostic contrast.

Indications for Use

The SINC™ Support Catheters are intended to be used in conjunction with steerable guidewires to access discrete regions of the peripheral vasculature. They may be used to facilitate placement and exchange of guidewires and other interventional devices and provide a conduit for delivery of saline solutions or diagnostic/ therapeutics agents.

Indications for Use Comparison

The SINC™ Support Catheter indications for use are identical to the predicate device indications for use.

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Technological Comparison

The SINC™ Support Catheter is nearly identical to the predicate device platform (spex LP, K200094). Like the predicate device, the SINC™ Support Catheter is intended for use in the peripheral vasculature to facilitate placement and exchange of guidewires. .

The subject and predicate devices are based on the following identical technological elements:

- all delivered to the target site using an over-the-wire percutaneous technique
- all have a through lumen to allow passage and exchange of guidewires
- all have a smooth inner lumen to provide reduced friction for guidewire movement
- all have a polymer catheter shaft with specific geometry to control the torque and push movements associated with lesion crossing

The following technological differences exist between the subject and predicate devices:

- The distal tip of the SINC support catheter has been modified to include a side port.

Non-Clinical and/or Clinical Tests Summary & Conclusions

The following performance data were provided in support of the substantial equivalence (reference ISO 10555-1).

- Simulated Use Testing
- Dimensional Verification
- Leak Testing
- Bond Integrity
- Component Integrity
- Corrsion Testing
- Kink Resistance
- Torque Testing
- Particulate
- Catheter Flow Rate and Burst Testing
- Lubricity Characterization
- Packaging Testing
- Design Validation

The SINC™ Support Catheter met all specified criteria and did not raise new safety and performance questions. Based on the performance testing, the SINC™ Support Catheter was found to have a safety and effectiveness profile that is substantially equivalent to the predicate device.