August 22, 2025

Reflow Medical, Inc.
Angela Lamprey
Director, Regulatory Affairs
208 Avenida Fabricante
Suite 100
San Clemente, California 92672

Re: K251277
Trade/Device Name: CoraForce Microcatheter, CoraFlex Microcatheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: July 17, 2025
Received: July 18, 2025

Dear Angela Lamprey:

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.

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,

Jenny R. Katsnelson -S

Digitally signed by Jenny R. Katsnelson -S
Date: 2025.08.22 11:19:03 -04'00'

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

Enclosure

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)*
K251277

Device Name
CoraForce® and CoraFlex® Microcatheters (Cora Microcatheters)

Indications for Use *(Describe)*
The Cora Microcatheters are intended to be used in conjunction with steerable guidewires to access discrete regions of the coronary and peripheral vasculature. They may be used to facilitate placement and exchange of guidewires and other interventional devices and provide a conduit for the delivery of saline solutions of diagnostic contrast.

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.

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SPECIAL 510(K) SUMMARY

Submitter	Reflow Medical, Inc. 208 Avenida Fabricante, Suite 100 San Clemente, CA 92672 Contact person: Lori Grace Email: lgrace@reflowmedical.com Phone: (949)-481-0399
Date Prepared	April 23, 2025
Device	Name of the Device: CoraForce® and CoraFlex® Microcatheters (Cora Microcatheters) Common Name: Percutaneous Catheter Classification Name: Percutaneous Catheter Regulatory Class: 2 Product Code: DQY
Predicate Device	Predicate: coraForce and coraFlex Support Catheters (Cora Catheters) – K201811 No reference devices were used in this submission.
Description of the device	The CoraFlex and CoraForce Microcatheters (Cora Microcatheters) are single lumen catheters designed to access the peripheral and coronary vasculature. Each configuration has a hydrophilic coated coiled catheter with a braided support matrix, radiopaque distal tip, proximal luer, and "spin-friendly" strain relief. The Cora Microcatheters will also allow for the exchange of guidewires and provide a conduit for delivery diagnostic or therapeutic agents.
Indications for Use	The Cora Microcatheters are intended to be used in conjunction with steerable guidewires to access discrete regions of the coronary and peripheral vasculature. They may be used to facilitate placement and exchange of guidewires and other interventional devices and provide a conduit for the delivery of saline solutions of diagnostic contrast.

Summary of the technological characteristics of your device compared to the predicate device

The technological characteristics of the subject Cora Microcatheters are similar to the technological characteristics of the Cora Catheters previously cleared under K201811.

At a high level, the subject and predicate devices are based on the following same technological elements:

- Both are delivered to the target site using a over-the-wire percutaneous technique
- Both have a through lumen to allow passage and exchange of guidewires
- Both have smooth inner lumens to provide reduced friction for guidewire movement
- Both have polymer catheter shafts with specific geometries to control the torque and push movements associated with lesion crossing
- Both use a specialized distal tip to facilitate the crossing of the lesion
- Both have coiled catheter shafts to promote additional flexibility

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

- The subject device has a proximal "spin zone" intended to aid in pushability
- The subject device has an increased distal "floppy zone" intended to aid in trackability
- The subject device has an "spin-friendly" strain relief intended to allow users to grip and torque the device. Additionally, the spiral design of the strain relief gives the user a direction to torque the device

	Predicate – coraForce and coraFlex Support Catheter (K201811)	**Subject - CoraForce and CoraFlex Microcatheters (Cora Microcatheters)**
Indications for Use	The Cora Catheters are intended to be used in conjunction with steerable guidewires to access discrete regions of the coronary and peripheral vasculature. They may be used to facilitate placement and exchange of guidewires and other interventional devices and provide a conduit for the delivery of saline solutions of diagnostic contrast.	Same
Guidewire Compatibility	0.014”	Same
Sheath Compatibility	4F	Same
Catheter Length	135cm/150cm	Same
Catheter Shaft OD	Max 0.032” (nominal 0.029”)	The catheter OD tapers from Max 0.051” (nominal 0.050”) at the proximal end to Max 0.032” (nominal 0.029”) at the distal end.
Component Materials	Stainless Steel with PTFE Coating Stainless Steel with gold plating (coraForce) Polymers	Same
Tip	coraForce: rigid coraFlex: flexible	coraForce: rigid coraFlex: flexible
Coating Material	Lubricious	Same
Coating Length	60cm	Same
Packaging Configuration	HDPE backer card and coil in single poly/Tyvek Pouch	Same
Sterilization Method	Ethylene Oxide (EO)	Same

A brief discussion of the nonclinical tests submitted

The following bench testing was completed:

- Simulated Use
- Dimensional Verification
- Radiopacity
- Leak Testing
- Kink Resistance
- Corrosion Resistance
- Component Integrity
- Bond Integrity
- Particulate Testing
- Torque Testing
- Burst Testing
- Lubricity and Coating Integrity Testing
- Design Validation/Usability
- Sterility Testing
- Biocompatibility Assessment

The Cora Microcatheters met all specified criteria and did not raise new questions regarding safety and effectiveness compared to the predicate. Based on the performance testing, the Cora Microcatheters were found to be substantially equivalent to the predicate.

A brief discussion of the clinical data submitted

No clinical data is submitted.

Conclusions

The conclusions drawn from the non-clinical testing demonstrate that the CoraForce and CoraFlex Microcatheters are substantially equivalent to the legally marketed predicate devices.