August 28, 2026

Reflow Medical, Inc.
Angela Lamprey
Director, Regulatory Affairs
208 Avenida Fabricante
Suite 100
San Clemente, California 92688

Re: K262013
Trade/Device Name: Kiba CTO Crossing Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: PDU
Dated: June 15, 2026
Received: June 15, 2026

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 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,

LYDIA S. GLAW -S
Digitally signed by LYDIA S. GLAW -S
Date: 2026.08.28 14:00:00 -04'00'

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.

510(k) Number *(if known)*
K262013

Device Name
Kiba CTO Crossing Catheter

Indications for Use *(Describe)*
The Kiba CTO Crossing Catheter is intended to be used in conjuction with steerable guidewires to access discrete regions of the peripheral vasculature. It may be used to facilitate placement and exchange of guidewires and other interventional devices, including facilitation of the intraluminal placment of diagnostic/ interventional devices beyond stenotic lesions (including chronic total occlusions [CTOs]) and provide a conduit for delivery of saline solutions or diagnostic/therapeutic agents. The Kiba CTO Crossing Catheter is contraindicated for use in the coronary and cerebral 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.

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SPECIAL 510(K) SUMMARY

Submitter	Reflow Medical, Inc. 208 Avenida Fabricante, Suite 100 San Clemente, CA 92672 Contact person: Angela Lamprey Email: alamprey@reflowmedical.com Phone: (949)-481-0399
Date Prepared	June 10, 2026
Device	Name of the Device: Kiba CTO Crossing Catheter Common Name: Percutaneous Catheter Classification Name: Percutaneous Catheter Regulatory Class: 2 Product Code: PDU, DQY
Legally Marketed Device to which your firm is claiming equivalence	Predicate: K193596 Device Name: Wingman Crossing Catheter No reference devices were used in this submission.
Description of the device	The Kiba CTO Crossing Catheter is a device intended to provide additional support to a steerable guidewire when accessing discrete regions of the peripheral vasculature. The device consists of a support catheter with a radiopaque beveled guide-tip and a handle.
Intended use of the device	The Kiba CTO Crossing Catheter is intended to be used in conjunction with steerable guidewires to access discrete regions of the peripheral vasculature. It may be used to facilitate placement and exchange of guidewires and other interventional devices, including facilitation of the intraluminal placement of diagnostic/ interventional devices beyond stenotic lesions (including chronic total occlusions [CTOs]) and provide a conduit for delivery of saline solutions or diagnostic/therapeutic agents. The Kiba CTO Crossing Catheter is contraindicated for use in the coronary and cerebral vasculature.

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

The technological characteristics of the subject Kiba CTO Crossing Catheter are similar to the technological characteristics of the Wingman Crossing Catheter previously cleared under K193596.

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

- Lasercut stainless steel hypotube with a beveled tip
- Gold plated tip for radiopacity
- 14, 18, and 35 sizes
- Hydrophilic coating

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

- Replaced outer polymer jacket with a PET heat-shrink jacket
- Modify the handle from a nose and plunger to a luer hub

	Predicate – (Wingman Crossing Catheter, K193596)	**Subject – Kiba CTO Crossing Catheter**
Intended Use	The Wingman Crossing Catheters (14/14C/18/35) are intended to be used in conjunction with steerable guidewires to access discrete regions of the peripheral vasculature. It may be used to facilitate placement and exchange of guidewires and other interventional devices, including	Same

	facilitation of the intraluminal placement of diagnostic/ interventional devices beyond stenotic lesions (including chronic total occlusions [CTOs]) and provide a conduit for delivery of saline solutions or diagnostic/therapeutic agents.	
Guidewire Compatibility	0.014", 0.018", 0.035"	0.014", 0.018", 0.035"
Sheath Compatibility	WM 14C: 3Fr minimum WM 18: 4Fr minimum WM 35: 5Fr minimum	Kiba 14/18/35 4Fr minimum
Catheter Length	WM 14C: 90cm, 135cm, 150cm WM 18: 90cm, 135cm, 150cm WM 35: 65cm, 90cm, 135cm	Kiba 14: 90cm, 105cm, 135cm, 150cm Kiba 18: 90cm, 105cm, 135cm, 150cm Kiba 35: 90cm, 135cm
Catheter Shaft OD	WM 14C: 0.035" maximum WM 18: 0.05" maximum WM 35: 0.06" maximum	Kiba 14: 0.023" maximum Kiba 18: 0.033" maximum Kiba 35: 0.053" maximum
Component Materials	WM 14C: 17-7 Stainless Steel WM 18/35: 304 Stainless Steel Braided polyimide shaft Pebax extrusion ABS handle & plunger	Kiba 14/18/35 304 Stainless Steel Gold plating PET heatshrink Lexin resin luer Dynaflex G7960-1001 Strain Relief
Tip	Gold-plated beveled tip	Gold-plated beveled tip
Coating Material	Hydrophilic	Hydrophilic
Coating Length	WM 14C: 30cm WM 18: 30cm WM 35: 40cm	Kiba 14/18/35 40cm
Packaging Configuration	HDPE backer card and coil in single poly/Tyvek Pouch	HDPE backer card and coil in single poly/Tyvek Pouch
Sterilization Method	EO sterilization	EO sterilization

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 Kiba CTO Crossing Catheter met all specified criteria and did not raise new safety of performance questions. Based on performance and biocompatibility testing, the Kiba device was found to be substantially equivalent to the predicate device.

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 Kiba CTO Crossing Catheter is substantially equivalent to the legally marketed predicate device.