March 12, 2026

Rapid Medical Ltd.
Ina Gutman
QA/RA Senior Director
Carmel Building, P.O. Box 337
Yokneam, 2069205
Israel

Re: K253062
Trade/Device Name: Tigertriever 25 Revascularization Device
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NRY
Dated: February 8, 2026
Received: February 9, 2026

Dear Ina Gutman:

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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,

NAIRA MURADYAN -S

Naira Muradyan, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
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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)*
K253062

Device Name
Tigertriever 25 Revascularization Device

Indications for Use *(Describe)*
The Tigertriever 25 Revascularization Device is intended to restore blood flow by removing thrombus from a large intracranial vessel in patients experiencing ischemic stroke within 8 hours of symptom onset. Patients who are ineligible for thrombolytic drug therapy or who failed thrombolytic drug therapy are candidates for treatment.

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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510(k) Summary
K253062

Submission Sponsor

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Date Prepared

March 10, 2026

Device Identification

Trade/Proprietary Name: Tigertriever 25 Revascularization Device
Common/Usual Name: Catheter, Thrombus Retriever
Classification Name: Percutaneous Catheter
Regulation Number: 21 CFR 870.1250
Product Code: NRY
Device Class: II
Classification Panel: Neurology

Legally Marketed Predicate and Reference Devices

Predicate Device: Tigertriever 21 Revascularization Device (K203592)
Reference Devices: Solitaire X Revascularization Device (K203358)
Aristotle 18 Guidewire (K231954)
ERIC™ Retrieval Device (K211120)

Indications for Use Statement

The Tigertriever 25 Revascularization Device is intended to restore blood flow by removing thrombus from a large intracranial vessel in patients experiencing ischemic stroke within 8 hours of symptom onset. Patients who are ineligible for thrombolytic drug therapy or who failed thrombolytic drug therapy are candidates for treatment.

Device Description

The Tigertriever 25 Revascularization Device (TRPP7125) is a line extension of the existing Tigertriever 21 Revascularization Device (TRPP7155), cleared as "Tigertriever Revascularization Device" under K203592. The Tigertriever 25 Revascularization Device is a stentriever that is comprised of an adjustable nitinol braided mesh, stainless steel shaft, nitinol core wire and a handle. The shaft connects the mesh and the handle by the core wire that runs inside the shaft from the distal end of the mesh to the slider activation element in the handle. The mesh is expanded when the physician pulls the slider, since the wires of the mesh are completely radiopaque, the physician sees the mesh under fluoroscopy and controls it until it conforms to the vessel diameter. The design of the wire mesh is optimized to penetrate the clot and encapsulate it during retrieval. The Tigertriever 25 revascularization device is supplied sterile and is intended for single-use only by physicians trained in neurointerventional procedures and the treatment of ischemic stroke.

Comparison of Technological Characteristics

The subject device has similar technological characteristics and the same principles of operation as the predicate device, the Tigertriever 21 Revascularization Device. Both stentriever models are comprised of a nitinol braided mesh, stainless steel shaft, nitinol core wire, and a handle. The table below compares the indications for use, principles of operation, technological characteristics, and materials of the Tigertriever 25 Revascularization Device with those of the predicate device, the Tigertriever 21 Revascularization Device. The technological differences of the Tigertriever 25 Revascularization Device do not raise any new questions of safety or effectiveness compared to the predicate device.

	Tigertriever 25 Revascularization Device (Subject device)	**Tigertriever 21 Revascularization Device (Predicate device)**
510(k) Number	K253062	K203592
Regulation	21 CFR 870.1250	21 CFR 870.1250
Product Code	NRY	NRY

	Tigertriever 25 Revascularization Device (Subject device)	Tigertriever 21 Revascularization Device (Predicate device)
Indications for Use	The Tigertriever 25 Revascularization Device is intended to restore blood flow by removing thrombus from a large intracranial vessel in patients experiencing ischemic stroke within 8 hours of symptom onset. Patients who are ineligible for thrombolytic drug therapy or who failed thrombolytic drug therapy are candidates for treatment.	The Tigertriever 21 Revascularization Device is intended to restore blood flow by removing thrombus from a large intracranial vessel in patients experiencing ischemic stroke within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA), or who fail IV t-PA therapy, are candidates for treatment.
Recommended Vessel Size	2.5mm - 6mm	2.5mm - 6mm
Anatomical Location	Neurovasculature	Neurovasculature
Mode of Operation	Manual expansion of the braided distal portion into the clot using the handle component	Manual expansion of the braided distal portion into the clot using the handle component
Design of Distal Portion	Close end braided nitinol mesh, manually expandable	Close end braided nitinol mesh, manually expandable
Stent Length (Unexpanded Configuration)	53 mm	32 mm
Stent Distal OD (Unexpended and Expanded Configurations)	Unexpanded configuration 1.5 mm Expanded configuration 7.5 mm	Unexpended configuration 1.5 mm Expanded configuration 6 mm
Overall length	226 cm	224 cm
Compatibility	Microcatheter with a minimum inner diameter of 0.025 inches	Microcatheter with a minimum inner diameter of 0.021 inches
Accessory Devices	Two insertion loading sheaths are provided, one is located on the device mesh and one is provided within the product package.	Three insertion loading sheaths are provided, one is located on the device mesh and two are provided within the product package.
Stent (Mesh) Material	Nitinol	Nitinol
Markers Material	90% Platinum/ 10% Iridium	90% Platinum/ 10% Iridium

	Tigertriever 25 Revascularization Device (Subject device)	Tigertriever 21 Revascularization Device (Predicate device)
Core Wire Material	Nitinol core wire coated with Green Lubriskin PTFE	Nitinol core wire coated with Green Lubriskin PTFE
Shaft Material	304 Stainless Steel	304 Stainless Steel
Insertion Loading Sheath Material	PTFE natural	PTFE natural
Sterilization Method	Ethylene oxide	Ethylene oxide
Single Use	Yes	Yes
Packaging	Placed into a Dispenser hoop, blister Tyvek pouch, and Carton box	Placed into a Dispenser hoop, blister Tyvek pouch, and Carton box

Non-Clinical Tests

In order to demonstrate safety and effectiveness of the device and to show substantial equivalence to the predicate devices, Rapid-Medical Ltd. completed a number of non-clinical bench tests and a GLP non-clinical evaluation study in a swine model.

Bench Tests

The device passed all non-clinical performance bench testing in accordance with internal requirements, national standards and international standards as shown in the table below to support substantial equivalence of the device.

Performance Bench Testing		
Test	**Test Method Summary**	**Results**
Simulated Use	Simulated use testing was performed in an in vitro neurovascular model.	All devices passed the acceptance criteria.
Radial Force	The radial force of the subject device was measured within a range of lumen diameters applicable to the intended vasculature and compared with the radial forces measured for the predicate device.	All devices passed the acceptance criteria.
Durability Testing	Damage was evaluated after delivery and withdrawal of the device beyond the number of passes and resheathings recommended in the instructions for use.	All devices passed the acceptance criteria.
Delivery, Deployment and Retrieval forces	The forces required to deliver, deploy, and retrieve the device were evaluated in an in vitro neurovascular model.	All devices passed the acceptance criteria.

Torque Strength Testing	The ability of the device to endure turns without failure was evaluated.	All devices passed the acceptance criteria.
Dimensions Test	Test samples were examined to verify that the dimensions of the Tigertriever 25 Revascularization Device are in compliance with specifications.	All devices passed the acceptance criteria.
Tip Flexibility	The tip deflection maximum force of the device was evaluated.	All devices passed the acceptance criteria.
Kink Resistance Testing	Kink resistance is tested along the device.	All devices passed the acceptance criteria.
Tensile Strength	The tensile strength was evaluated for all joints.	All devices passed the acceptance criteria.
Particulates Evaluation	The number and size of particulates following simulated use of the device in a neurovascular model was evaluated.	Similar to the predicate.
Af Temperature Evaluation	The Austenite Finish (Af) temperature value of the device was evaluated.	All devices passed the acceptance criteria.
Corrosion Resistance	The corrosion of the device is evaluated when tested according to the method in Annex B of ISO 11070:2014(E).	All devices passed the acceptance criteria.
Coating Integrity	The PTFE coating was evaluated following simulated use.	All devices passed the acceptance criteria.
Usability Test	Physicians evaluated the devices under simulated use conditions to assess their usability criteria.	All devices passed the acceptance criteria.

Biocompatibility

Biocompatibility testing was completed for the Tigertriever 25 Revascularization Device in accordance with ISO 10993 and consisted of the following tests:

Test	**Test Description**	**Result Summary**	**Conclusion**
Cytotoxicity	Cytotoxicity Study using MEM Elution	The test article extract showed no evidence of causing cell lysis or toxicity. The test article showed no cytotoxic potential.	Pass

Irritation (Intracutaneous Reactivity)	ISO Intracutaneous Irritation Study using extracts	Test article met the requirements of the test with no differences between each test article extract overall mean score and corresponding control extract mean score.	Pass
Sensitization	ISO Guinea Pig Maximization Sensitization Test	Test articles showed no evidence of causing delayed dermal contact sensitization. Test article is not considered a sensitizer.	Pass
Hemocompatibility – Hemolysis	ASTM Hemolysis Study – Extract and Direct Contact	The test articles in direct and indirect contact with blood were non-hemolytic.	Pass
Hemocompatibility – Complement Activation	SC5b-9 Complement Activation Assay	The test article was not considered to be a potential activator of the complement system.	Pass
Pyrogenicity	USP Rabbit Pyrogen Study, Material Mediated	The total rise of rabbit temperatures during the observation period was within acceptable USP limits. The test article was judged as nonpyrogenic.	Pass
Acute Systemic Toxicity	ISO Acute Systemic Toxicity in Mice	No mortality or evidence of systemic toxicity from extracts injected into mice.	Pass
Thrombogenicity	GLP Safety Study in the Swine Model	No evidence of device-related thrombogenicity and performed similarly to the control Device.	Pass

All tests confirmed that the Tigertriever 25 Revascularization Device met biological safety requirements per the ISO 10993 standard.

Pre-Clinical Animal Testing Data

A Good Laboratory Practice (GLP) preclinical study in a swine model (n=6) was conducted to evaluate the safety, thrombogenicity, and clot retrieval performance of the Tigertriever 25 Revascularization Device compared to a reference device at 3-day and 30-day timepoints. The study evaluated bilateral renal, ascending pharyngeal, internal maxillary, and lingual arteries with both hard and soft clot retrieval. The Tigertriever 25 achieved effective clot retrieval with device visibility, deliverability, and TICI scores comparable to the reference device. No vessel perforations, dissections, or device-related thrombus formation were observed. Histopathological evaluation showed minimal to mild arterial changes consistent with expected responses to mechanical intervention, comparable between test and control groups, and assessed as non-adverse with appropriate healing observed over the study duration. Thrombogenicity testing in lingual arteries demonstrated no evidence of device-related thrombosis. At termination, one vessel in the test group was noted to be occluded; histopathology indicated this was organizing procedural clot material rather than new device-related thrombosis. Study endpoints were met and the Tigertriever 25 demonstrated no evidence of clinically relevant vessel injury, thrombosis, or inflammation, and showed safety and thromboresistance comparable to the reference device, supporting substantial equivalence.

Sterilization and Shelf Life

The device and its accessories underwent sterilization validation studies in accordance with ISO 11135: 2014/AC: 2014 ("Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices") requirements to demonstrate that the Ethylene Oxide (EtO) sterilization process will reliably sterilize the product loads to a Sterility Assurance Level (SAL) of 10^{-6} or less, according to the overkill half cycle approach and relevant standards.

The device and package shelf-life studies were performed to demonstrate that the device and package had a 2.5-year shelf life.

The Tigertriever 25 Revascularization device and package met all acceptance criteria for these studies, and therefore will have a shelf life of 2.5 years.

Clinical Performance Data

No clinical studies were conducted. Substantial equivalence of the Tigertriever 25 Revascularization device to the predicate device is established through the results of non-clinical testing.

Statement of Substantial Equivalence

The Tigertriever 25 Revascularization device has the same intended use, indications for use, and similar technological characteristics when compared to the predicate Tigertriever 21 Revascularization Device. The technological differences do not raise any new questions

regarding the safety and effectiveness of the device. The safety and performance of the Tigertriever 25 Revascularization device were confirmed to be similar to the predicate device through the non-clinical bench and animal testing discussed above. Therefore, the subject device is substantially equivalent to the predicate device.