August 28, 2026

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

Re: K260617
Trade/Device Name: Tigertriever 13 Ultra Revascularization Device
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NRY
Dated: July 28, 2026
Received: July 28, 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 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,

NAIRA MURADYAN -S

Naira Muradyan, PhD
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional, and
Neurodiagnostic Devices
OHT5: Office of Neurological and
Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260617

Please provide the device trade name(s).

Tigertriever 13 Ultra Revascularization Device

Please provide your Indications for Use below.

The Tigertriever 13 Ultra 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.

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

K260617

Submission Sponsor

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Date Prepared

August 24, 2026

Device Identification

Trade/Proprietary Name: Tigertriever 13 Ultra 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 Device

Predicate Device: Tigertriever 13 Revascularization Device (K220808)

Indications for Use Statement

The Tigertriever 13 Ultra 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 13 Ultra Revascularization Device ("Tigertriever 13 Ultra") is part of the Tigertriever family of stent retrievers and incorporates the same fundamental design and mechanism of action as the predicate device.
The device consists of a manually expandable nitinol braided mesh attached to a stainless steel shaft, with a nitinol core wire extending from the distal mesh to the proximal handle. The handle incorporates a rotating knob mechanism that enables controlled expansion of the mesh under fluoroscopic guidance. The radiopaque mesh allows visualization during deployment to ensure apposition to the vessel wall.
The device is designed to penetrate and encapsulate thrombus for retrieval. It is supplied sterile, single-use, and intended for use by physicians trained in neurointerventional procedures.

Comparison of Technological Characteristics

The Tigertriever 13 Ultra has the same intended use, operating principle, materials, and fundamental design as the predicate Tigertriever 13 device (K220808).
The primary difference is the proximal handle design, which has been modified from a slider mechanism (predicate) to a rotating knob mechanism (subject device). This modification does not affect the distal mesh design, materials, or mechanism of clot engagement and retrieval.
The subject device does not raise new questions of safety or effectiveness compared to the predicate device.

	Tigertriever 13 Ultra Revascularization Device (Subject device)	**Tigertriever 13 Revascularization Device (Predicate device)**
510(k) Number	K260617	K220808
Regulation No.	21 CFR 870.1250	21 CFR 870.1250
Regulation Name	Percutaneous catheter	Percutaneous catheter
Classification	Class II	Class II
Product Code	NRY	NRY
Indications for Use	The Tigertriever 13 Ultra 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 13 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.

	Tigertriever 13 Ultra Revascularization Device (Subject device)	Tigertriever 13 Revascularization Device (Predicate device)
Recommended vessel size	1.5 mm – 2.5 mm	1.5 mm – 2.5 mm
Anatomical Location	Neurovasculature	Neurovasculature
Technological Characteristics		
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 the distal portion	Close end braided nitinol mesh, manually expandable	Close end braided nitinol mesh, manually expandable
Stent length (un-expanded configuration)	20.5 mm	20.5 mm
Overall length (Total length of the device from handle's distal end to the tip)	233 cm	233 cm
Proximal Handle Design	Rotating knob activation mechanism	Slider activation mechanism
Compatibility	Microcatheter with an internal diameter of 0.0165 inches	Microcatheter with an internal diameter of 0.0165 inches
Accessory Devices	Two insertion loading sheaths are provided, one is located on the device mesh and one is provided within the product package	Two insertion loading sheaths are provided, one is located on the device mesh and one is provided within the product package
Materials		
Stent (mesh)	Nitinol	Nitinol
Markers	90% Platinum/ 10% Iridium	90% Platinum/ 10% Iridium
Core wire	Nitinol core wire coated with Green Lubriskin PTFE	Nitinol core wire coated with Green Lubriskin PTFE
Shaft	304 Stainless Steel	304 Stainless Steel
Insertion loading sheath	PTFE - Blue Translucent color Pantone 2144C	PTFE natural
Packaging		
Sterilization Method	Ethylene oxide	Ethylene oxide
Single Use	Yes	Yes
Packaging	Placed into a Dispenser hoop, Tyvek pouch, and Carton box	Placed into a Dispenser hoop, blister, Tyvek pouch, and Carton box

Non-Clinical Tests

Bench Testing

Non-clinical bench testing was performed to evaluate device performance and to support substantial equivalence to the predicate device. All testing met predefined acceptance criteria.

Performance Bench Testing		
Test	**Test Method Summary**	**Results**
Device Performance (Simulated Use)	An in vitro neurovascular model used to evaluate clot retrieval performance under representative anatomical conditions.	Successful recanalization achieved within predefined acceptance criteria. No device malfunction or structural anomalies observed.
Radial Force	Radial force was measured at clinically relevant vessel diameters and compared to established predicate performance benchmarks.	Radial force values were within a predefined comparative performance range relative to predicate device.
Durability Testing	Repeated deployment and retrieval cycles were performed to evaluate functional integrity following labeled use conditions.	Devices completed required deployment cycles without structural damage or performance degradation.
Delivery, Deployment, and Retrieval Forces	Forces required to deliver, deploy, and retrieve the device were measured in an in vitro neurovascular model.	Measured forces were within predefined acceptance limits.
Dimensional Verification	Critical device dimensions are measured to confirm conformity to design specifications.	All measured dimensions met predefined specification limits.
Tensile Strength	Tensile strength testing was performed on bonded interfaces and critical joints.	All joints exceeded minimum strength requirements.
Usability Evaluation	Simulated clinical use evaluation conducted by physicians to assess handle interaction and device control.	All predefined usability acceptance criteria were met. No critical use errors observed.

Biocompatibility

Biocompatibility of the Tigertriever 13 Ultra is supported by previously completed testing. The patient-contacting materials, duration of contact, and nature of contact remain unchanged. The same PTFE loading sheath with blue color additives is also used in the Rapid Medical Tigertriever 25 device (K253062). Therefore, no additional biocompatibility testing was conducted.

Pre-Clinical Animal Testing Data

No animal testing was conducted for the Tigertriever 13 Ultra. The modifications do not affect the device's mechanism of action, distal design, or intended use.

Sterilization

The Tigertriever 13 Ultra is sterilized using ethylene oxide (EO). The device is provided sterile with a sterility assurance level (SAL) of 10^{-6}.

The validated EO sterilization cycle previously reviewed and accepted for the Tigertriever family (K220808) remains applicable. A product adoption assessment was conducted in accordance with AAMI TIR28, and EO residual testing confirmed compliance with ISO 10993-7 limits.
No changes were made to the sterilization method or cycle parameters.

Shelf Life

A shelf life of two and a half (2.5) years is claimed for the Tigertriever 13 Ultra.

Shelf-life support is based on a device-specific shelf-life validation study performed directly on the final, finished Tigertriever 13 Ultra device, following two ethylene oxide sterilization cycles, simulated transit conditions, and accelerated aging equivalent to 2.5 years. This study evaluated dimensional conformance, radial force, tensile strength, durability, simulated use, and delivery/deployment/retrieval force performance of the final device; all tests met their predefined acceptance criteria. Device-specific packaging validation and transportation simulation testing further confirmed that the pouch-only sterile barrier system maintains seal integrity and package performance following sterilization, conditioning, and simulated distribution.

Real-time aging studies are ongoing in accordance with established protocols.

Clinical Performance Data

No clinical studies were conducted for the Tigertriever 13 Ultra. The device modifications do not affect intended use, mechanism of action, or fundamental technology, and substantial equivalence is supported by non-clinical testing.

Statement of Substantial Equivalence

The Tigertriever 13 Ultra Revascularization Device is substantially equivalent to the legally marketed Tigertriever 13 device.
The Tigertriever 13 Ultra has the same intended use, indications for use, mechanism of action, and fundamental technological characteristics as the predicate device.
Performance bench testing and supporting non-clinical evaluations demonstrate that the Tigertriever 13 Ultra performs in accordance with established design specifications and does not raise new questions of safety or effectiveness.
Accordingly, the Tigertriever 13 Ultra is substantially equivalent to the predicate device.