



October 6, 2025

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

Re: K251603

Trade/Device Name: Tigertriever 17 Ultra Revascularization Device  
Regulation Number: 21 CFR 870.1250  
Regulation Name: Percutaneous Catheter  
Regulatory Class: Class II  
Product Code: NRY  
Dated: September 4, 2025  
Received: September 4, 2025

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 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](mailto: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

510(k) Number (if known)

K251603

Device Name

Tigertriever 17 Ultra Revascularization Device

Indications for Use (Describe)

The Tigertriever 17 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.

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.

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## **510(k) Summary K251603**

### **Submission Sponsor**

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### **Contacts**

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### **Date Prepared**

August 26, 2025

### **Device Identification**

**Trade/Proprietary Name:** Tigertriever 17 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 and Reference Devices**

Predicate Device: Tigertriever 17 Revascularization Device (K203592)  
Reference Device: Solitaire X Revascularization Device (K203358)

### **Indications for Use Statement**

The Tigertriever 17 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 17 Ultra Revascularization Device (TRPP7266) is a line extension of the existing Tigertriever 17 Revascularization Device (TRPP7166) cleared under K203592. The Tigertriever 17 Ultra 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 17 Ultra 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 the same principles of operation and indication for use as the predicate device. The subject device has different technological characteristics compared to the predicate device, the Tigertriever 17 Revascularization Device, namely a longer mesh length and a slightly larger microcatheter compatibility. 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 17 Ultra Revascularization Device with that of the predicate device (the Tigertriever 17 Revascularization Device). The technological differences of the Tigertriever 17 Ultra Revascularization Device do not raise any new questions of safety or effectiveness compared to the predicate device.

	<b>Tigertriever 17 Ultra Revascularization Device (TRPP7266, Subject Device)</b>	<b>Tigertriever 17 Revascularization Device (TRPP7166, Predicate Device)</b>
510(k) Number	K251603	K203592
Regulation	21 CFR 870.1250	21 CFR 870.1250
Product Code	NRY	NRY

	<b>Tigertriever 17 Ultra Revascularization Device (TRPP7266, Subject Device)</b>	<b>Tigertriever 17 Revascularization Device (TRPP7166, Predicate Device)</b>
Indications for Use	The Tigertriever 17 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 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.
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)	32 mm	23 mm
Stent Distal OD (Unexpanded and Expanded Configurations)	Unexpanded configuration 0.5 mm Expanded configuration 3 mm	Unexpanded configuration 0.5 mm Expanded configuration 3 mm
Overall Length	224 cm	200 cm
Microcatheter Compatibility	Microcatheter with a minimum inner diameter of 0.017 inches	Microcatheter with a minimum inner 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.	Three insertion loading sheaths are provided, one is located on the device mesh and two are provided within product package.
Stent (Mesh) Material	Nitinol	Nitinol
Markers Material	90% Platinum/ 10% Iridium	90% Platinum/ 10% Iridium
Core Wire Material	Nitinol core wire coated with Green Lubriskin PTFE	Nitinol core wire coated with Green Lubriskin PTFE

	<b>Tigertriever 17 Ultra Revascularization Device (TRPP7266, Subject Device)</b>	<b>Tigertriever 17 Revascularization Device (TRPP7166, Predicate Device)</b>
Shaft Material	304 Stainless Steel	304 Stainless Steel
Insertion Loading Sheath Material	PTFE (Natural color)	PTFE (Natural color)
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 Performance Data**

In order to demonstrate safety and effectiveness of the subject device and to show substantial equivalence to the predicate device, Rapid Medical Ltd. completed a number of non-clinical tests.

#### Bench Tests

The device passed all 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.

<b>Performance Bench Testing</b>		
<b>Test</b>	<b>Test Method Summary</b>	<b>Results</b>
Simulated Use	Simulated use testing of the Tigertriever 17 Ultra Revascularization Device was performed in an anatomical model which simulated the tortuosity of the neurovasculature. Devices were delivered through the tortuous anatomical model to evaluate the effectiveness of the device at retrieval of firm and soft clots.	The subject device retrieved clots and restored flow in the test model.
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.	The radial force of the subject device when tested in applicable lumen sizes is comparable to the predicate device.
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.	Devices tested demonstrated no damage after delivery and withdrawal testing.

Delivery, Deployment and Retrieval forces	The forces required to deliver, deploy, and retrieve the device were evaluated in an in vitro neurovascular model.	The subject device demonstrated acceptable performance with respect to delivery, deployment and retrieval.
Torque Strength Testing	The ability of the device to endure turns without failure was evaluated.	All devices passed acceptance criteria.
Dimensions Test	Test samples were examined to verify that the dimensions of the Tigertriever 17 Ultra devices are in compliance with specifications.	All devices passed acceptance criteria.
Tip Flexibility	The tip deflection maximum force of the device was evaluated.	All devices passed acceptance criteria and were comparable to the predicate device.
Kink Resistance Testing	Kink resistance is tested along the device.	All devices passed acceptance criteria.
Tensile Strength	The tensile strength was tested for all joints.	All devices passed acceptance criteria.
Particulates Evaluation	The number and size of particulates following simulated use of the device in a neurovascular model were evaluated.	The particulate generated by the subject device was similar to the particulate generated by the predicate device.
Austenite Finish (Af) Temperature Evaluation	Data from predicate submission is used because of similarities in device design.	All devices passed acceptance criteria.
Corrosion Resistance	Data from predicate submission is used because of similarities in device design.	All devices passed acceptance criteria.

### Biocompatibility

Biocompatibility testing conducted supports the biocompatibility of the Tigertriever 17 Ultra Revascularization Device in accordance with ISO 10993 and consisted of the following tests conducted on various models of the Tigertriever devices, which were considered worst-case in terms of overall design and included the same materials and manufacturing processes as the Tigertriever 17 Ultra Revascularization Device:

<b>Test</b>	<b>Test Description</b>	<b>Result Summary</b>	<b>Conclusion</b>
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
Hemocompatibility – Thrombogenicity	Acute Pre-Clinical Evaluation of the Safety of Tigertriever device in a Swine Model Thrombogenicity	Data from predicate submission is used.	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

All tests confirmed that the Tigertriever 17 Ultra Revascularization Device met biological safety requirements per the ISO 10993 standard.

#### Pre-Clinical Animal Testing Data

No animal studies were conducted, as substantial equivalence of the Tigertriever 17 Ultra Revascularization Device to the predicate device is established through the results of non-clinical performance testing.

#### Sterilization and Shelf Life

The subject device and its accessories are sterilized using an ethylene oxide sterilization cycle that was verified to a sterility assurance level of  $1 \times 10^{-6}$  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”). The subject device and package shelf-life studies established that the subject device and packaging remain functional for the labeled expiration date.

#### **Clinical Performance Data**

No clinical studies were conducted, as substantial equivalence of the Tigertriever 17 Ultra Revascularization Device to the predicate device is established through the results of non-clinical performance testing.

#### **Statement of Substantial Equivalence**

The Tigertriever 17 Ultra Revascularization Device has the same intended use, indications for use, and similar technological characteristics as the predicate Tigertriever 17 Revascularization Device. The technological differences do not raise new questions regarding the safety or effectiveness. Performance data demonstrate that the subject Tigertriever 17 Ultra Revascularization Device is substantially equivalent to the predicate device.