April 17, 2023

Rapid Medical Ltd.
Orit Yaniv, Ph.D.
VP RA/QA
Carmel Building, P.O. Box 337
Yokneam, 2069205
Israel

Re: K230429
Trade/Device Name: Tigertriever 21 Revascularization Device, Tigertriever 17 Revascularization Device, Tigertriever 13 Revascularization Device
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NRY
Dated: March 20, 2023
Received: March 20, 2023

Dear Orit Yaniv:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,
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

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)*
K230429

Device Name
Tigertriever 21 Revascularization Device, Tigertriever 17 Revascularization Device, Tigertriever 13 Revascularization Device

Indications for Use *(Describe)*
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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

K230429

Manufacturer/Sponsor: Rapid Medical Ltd.
Carmel Building, P.O. Box 337
Yokneam, 2069205 Israel

Phone: +972-72-250-3331
Facsimile: +972-72-250-3332

Contact: Orit Yaniv, Ph.D.
VP RA/QA
+972-72-250-3331
Orit@rapid-medical.com

Date Prepared: April 12, 2023

Device Trade Name: Tigertriever 21 Revascularization Device, Tigertriever 17 Revascularization Device, Tigertriever 13 Revascularization Device

Common/Usual Name: Catheter, Thrombus Retriever

Classification: 21 CFR 870.1250, Percutaneous Catheter

Class: II

Product Code: NRY

Predicate Devices: Tigertriever and Tigertriever 17 Revascularization Device (K203592)
Tigertriever 13 Revascularization Device (K220808)

Indications for Use:
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.

Device Description:
The Tigertriever 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 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 with the Predicate Devices:
The Tigertriever 21, Tigertriever 17, Tigertriever 13 Revascularization Devices subject to this submission are substantially equivalent to the predicate devices, Tigertriever and Tigertriever 17 Revascularization Device (K203592) and Tigertriever 13 Revascularization Device (K220808), based on the same indications for use, device design, materials, manufacturing, packaging and sterilization methods, and similar technological characteristics. A comparison of the subject device with the predicate devices is summarized in Table 1 below.

Table 1: Substantial Equivalence - Predicate Comparison

	Predicate devices			**Subject devices**		
Device Name	**Tigertriever TRPP7155**	**Tigertriever 17 TRPP7166**	**Tigertriever 13 TRPP7144**	**Tigertriever 21 TRPP7155**	**Tigertriever 17 TRPP7166**	**Tigertriever 13 TRPP7144**
510(k) Number	K203592		K220808	K230429		
Regulation No.	21 CFR 870.1250			Same		
Regulation Name	Percutaneous Catheter			Same		
Classification	Class II			Same		
Product Code	NRY			Same		
Indications for Use	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.			Same		
Anatomical Location	Neurovasculature			Same		
Technological Characteristics						
Mode of Operation	Manual expansion of the braided distal portion into the clot using the handle component			Same		
Design of Distal Portion	Close end braided nitinol mesh, manually expandable			Same		
Stent Length (un-expanded configuration)	32 mm	23 mm	20.5 mm	32 mm	23 mm	20.5 mm
Stent Size Distal OD (Unexpanded and Expanded Configuration)	Unexpanded configuration 1.5 mm Expanded configuration 6 mm	Unexpanded configuration 0.5 mm Expanded configuration 3 mm	Unexpanded configuration 0.5 mm Expanded configuration 2.5 mm	Unexpanded configuration 1.5 mm Expanded configuration 6 mm	Unexpanded configuration 0.5 mm Expanded configuration 3 mm	Unexpanded configuration 0.5 mm Expanded configuration 2.5 mm

Stent Structure	Braided from twelve (12) Niti DFT 0.075 mm wires with a tantalum core	Braided from eight (8) Niti DFT 0.075 mm wires with a tantalum core	Braided from eight (8) Niti DFT 0.05 mm wires with a platinum core	Braided from twelve (12) Niti DFT 0.075 mm wires with a tantalum core	Braided from eight (8) Niti DFT 0.075 mm wires with a tantalum core	Braided from eight (8) Niti DFT 0.05 mm wires with a platinum core
Overall Length (shaft+cable+ mesh+tip)	212 cm	208 cm	228 cm	218 cm	218 cm	228 cm
Fluorosafe Markers on Shaft	No			Yes		
Compatibility	Microcatheter with an internal diameter of 0.021 inches	Microcatheter with an internal diameter of 0.017 inches	Microcatheter with an internal diameter of 0.0165 inches	Microcatheter with an internal diameter of 0.021 inches	Microcatheter with an internal diameter of 0.0165 inches	Microcatheter with an internal diameter of 0.0165 inches
Materials						
Stent (mesh)	Nitinol			Same		
Markers	90% Platinum/ 10% Iridium			Same		
Core wire (shaft)	Nitinol core wire and 304 Stainless Steel shaft			Same		
Introducer sheath	PTFE			Same		
Packaging						
Sterilization Method	Ethylene oxide			Same		
Single Use	Yes			Same		
Packaging	Placed into a Dispenser hoop, blister, Tyvek pouch, and Carton box			Same		

The differences between the subject and predicate devices do not raise new questions of safety and effectiveness and are evaluated through the nonclinical testing referenced below.

Nonclinical Performance Testing:

Bench Tests:

Table2: Bench testing

Performance Bench Testing		
Test	**Test Method Summary**	**Conclusions**
Simulated use test	Simulated use testing of the Tigertriever 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 device was tested for handling and clot retrieval in an *in vitro* tortuous path anatomical model, which has been used in the evaluation of the predicate device. The subject device effectively retrieved clot and restored flow in the test model.

Durability	Damage was evaluated after delivery and withdrawal of the device beyond the recommended number of passes and resheathings recommended in the instructions for use.	Devices tested demonstrated no damage after delivery and withdrawal testing. Durability established acceptable performance for 3 passes, which is at least equivalent to the number of passes specified in the predicate labeling (2 passes per device).
Delivery, deployment and retrieval	The delivery, deployment and retrieval forces were measured during simulated use of the subject device.	The device was tested for delivery, deployment, and retrieval in an *in vitro* tortuous path anatomical model, which has been used in the evaluation of the predicate device. The subject device demonstrated acceptable performance with respect to delivery, deployment and retrieval.
Dimensions test	Dimensional conformance to specifications was confirmed.	The subject device dimensions are within the range of existing predicate device dimensions. The minor differences in dimensions do not affect performance, safety or effectiveness.
Tensile test	The minimum force to break the subject device was tested for the handle joint.	The tensile strength of the device met acceptance criteria based on recognized standards (ISO 10555-1).
Particulate test	Particulate test was performed according to the light obscuration test method.	The particulate generated by the subject device was similar to the particulate generated by the predicate device.

Biocompatibility Testing:

Biocompatibility tests were repeated with a representative Tigertriever device that contains the new fluorosafe markers and shares the same overall design and materials as the three subject device models and represents the worst case in terms of biocompatibility.

All biocompatibility tests met the acceptance criteria.

Table3: Biocompatibility testing results and methodology

Biological Endpoint	**Test Results**	**Conclusion**
Cytotoxicity	Pass. Grade 0 reactivity observed 48 hours post exposure to test article extract.	Non-cytotoxic
Irritation (Intracutaneous Reactivity)	Pass. Difference of overall mean score between test article and control was 0.	Non-irritant
Sensitization (Guinea Pig Maximization Test)	Pass. Grade 0, no evidence of causing delayed dermal contact sensitization.	Does not elicit sensitization response
Hemocompatibility - Complement activation Assay	SC5b-9 concentration of the test article sample was statistically less than the positive control and was not statistically higher than the	Pass

	negative control.	
Hemocompatibility - In Vitro Hemolysis	Both the test article in direct contact with blood and the test article extract were non-hemolytic.	Non-hemolytic
Pyrogenicity (Material Mediated Pyrogenicity)	The total rise of rabbit temperatures during the 3-hour observation period was within acceptable USP limits.	Non-pyrogenic
ISO Systemic Toxicity Testing Study in Mice	No mortality or evidence of systemic toxicity from the extracts injected into mice.	Non-toxic

Sterilization and Shelf Life:

The modifications to the Tigertriever Revascularization Device do not impact sterilization and established shelf-life of the product.

Clinical Testing:

A clinical study was not deemed necessary to evaluate the modifications to the Tigertriever Revascularization Device. Substantial equivalence of the subject devices has been established to the predicate devices through the results of nonclinical testing.

Conclusion:

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