July 25, 2022

Rapid Medical Ltd.
% Janice Hogan
Partner
Hogan Lovells US LLP
1735 Market Street, 23rd Floor
Philadelphia, Pennsylvania 19103

Re: K220808
Trade/Device Name: Tigertriever 13 Revascularization Device
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NRY
Dated: June 21, 2022
Received: June 21, 2022

Dear Janice Hogan:

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, 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
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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: 06/30/2023 *See PRA Statement below*

510(k) Number *(if known)*
K220808

Device Name
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.

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510(k) Summary

K220808

Submission Sponsor

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Date Prepared

July 15, 2022

Device Identification

Trade/Proprietary Name: Tigertriever 13 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(s)

Tigertriever and Tigertriever 17 Revascularization Device (K203592)

Indications for Use Statement

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 13 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 13 Revascularization Device is supplied sterile and is intended for single-use only by physicians trained in neuro-interventional catheterization and the treatment of ischemic stroke.

Comparison of Technological Characteristics with the Predicate Device

The Tigertriever 13 Revascularization Device is substantially equivalent to the Tigertriever 17 Revascularization Device (model: TRPP7166) previously cleared as part of K203592. The two devices have the same indications for use and principles of operation, and similar technological characteristics. There are minor differences in dimensions between the two device models; however, they provide physicians with a slightly broader range of lengths and diameters to accommodate the range of large vessel occlusion (LVO) dimensions. This difference in dimensions does not raise new questions of safety or effectiveness. A summary of the technological characteristics of the Tigertriever 13 Revascularization Device in comparison to those of the predicate device is presented in the table below.

	Tigertriever 17 Revascularization Device (TRPP7166) (Predicate device)	**Tigertriever 13 Revascularization Device (TRPP7144) (Subject device)**
510(k) Number	K203592	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

	Tigertriever 17 Revascularization Device (TRPP7166) (Predicate device)	**Tigertriever 13 Revascularization Device (TRPP7144) (Subject device)**
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.	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
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 distal portion	Close end braided nitinol mesh, manually expandable	Close end braided nitinol mesh, manually expandable
Stent length (un-expanded configuration)	23mm	20.5mm
Stent size Distal OD (unexpanded and expanded configuration)	Unexpanded configuration 0.5mm Expanded configuration 3mm	Unexpanded configuration 0.5mm Expanded configuration 2.5mm
Stent structure	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	228 cm (shaft+cable+mesh+tip)	208 cm (shaft+cable+mesh+tip)
Compatibility	Microcatheter with an internal diameter of 0.017 inches	Microcatheter with an internal diameter of 0.0165 inches
Materials		
Stent (mesh)	Nitinol	Nitinol
Markers	90% Platinum/ 10% Iridium	90% Platinum/ 10% Iridium
Core wire (shaft)	Nitinol core wire and 304 Stainless Steel shaft	Nitinol core wire and 304 Stainless Steel shaft
Introducer sheath	PTFE	PTFE
Packaging		
Sterilization Method	Ethylene oxide	Ethylene oxide

	Tigertriever 17 Revascularization Device (TRPP7166) (Predicate device)	**Tigertriever 13 Revascularization Device (TRPP7144) (Subject device)**
Single Use	Yes	Yes
Packaging	Placed into a Dispenser hoop, blister, Tyvek pouch, and Carton box	Placed into a Dispenser hoop, Tyvek pouch, and Carton box

Non-Clinical Performance Data

As part of demonstrating safety and effectiveness of the device and in showing substantial equivalence to the predicate device, Rapid Medical Ltd. completed a number of non-clinical performance tests. The device meets all the requirements of overall design, sterilization, and biocompatibility. Testing results confirm that the design output meets the design specification for the device.

Biocompatibility

Biocompatibility of the Tigertriever 13 was based on the biocompatibility testing data for the Comaneci Embolization Assist Device (DEN170064). The two devices share the same manufacturing process and same manufacturing environment. In addition, the two devices are intended to be used in the same anatomical locations and are identical in terms of frequency and duration of exposure. Biocompatibility testing was completed for Comaneci device and consisted of the following tests: Cytotoxicity, Irritation (Intracutaeous Reactivity), Sensitization, Hemocompatibility, Pyrogenicity, Acute Systemic and Toxicity Testing. In addition, in vivo thrombogenicity was performed for the Tigertriever model. Results of the biocompatibility testing indicate that Tigertriever 13 Revascularization Device is biocompatible and is substantially equivalent for its intended use.

Biological Endpoint	**Test Results**	**Conclusion**
Cytotoxicity – ISO Elution Method	Grade 0 reactivity observed 48 hours post exposure to test article extract.	Non-cytotoxic
Irritation – Intracutaeous Reactivity in Rabbit	Difference of overall mean score between test article and control was 0.	Non-irritant
Sensitization – Guinea Pig Maximization Test	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 lower than the activated NHS control ($p<0.05$), and was not statistically higher than the negative control.	Pass
Hemocompatibility – In Vitro Hemolysis	Test article = 0.0% hemolysis.	Non-Hemolytic

Biological Endpoint	Test Results	Conclusion
Pyrogenicity – Material Mediated Pyrogenicity in Rabbit	The total rise of rabbit temperatures during the 3-hour observation period was within acceptable USP limits.	Non-pyrogenic
Systemic Toxicity –Systemic Toxicity Study in Mice	No mortality or evidence of systemic toxicity from the extracts injected into mice.	Non-toxic
Thrombogenicity – Acute Pre-Clinical Evaluation of the Safety of Tigertriever device in a Swine Model Thrombogenicity	Test device did not show higher thrombogenicity rate compared to the predicate device.	Pass

Sterilization and Shelf life

The device and its accessories are sterilized by 100% Ethylene Oxide. The previously conducted shelf-life testing for the Tigertriever Revascularization Device supports a 2.5-year shelf life for the Tigertriever 13 Revascularization Device.

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. Results of the performance bench testing indicate that Tigertriever 13 Revascularization device meets established performance requirements and is substantially equivalent for its intended use.

Performance Bench Testing		
Test	**Test Method Summary**	**Conclusions**
Simulated use test	Simulated use testing of the Tigertriever 13 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.
Radial force	The radial force of the subject device was measured within a range of diameters from 1.5mm and 2.5mm, and compared with the radial forces measured for the predicate devices.	The radial force of the subject device when tested in applicable lumen sizes is comparable to the predicate device.
Durability	Damage was evaluated after delivery and withdrawal of the device beyond the recommended number of passes and	Devices tested demonstrated no damage after delivery and withdrawal testing. Durability established acceptable performance

Performance Bench Testing		
Test	**Test Method Summary**	**Conclusions**
	resheathings recommended in the instructions for use.	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.
Torque strength	Devices were tracked through a microcatheter in a tortuous path anatomical model and evaluated for damage following a number of rotations with the distal end constrained.	The device demonstrated the ability to withstand 5 rotations without damage. Like the predicate device, rotational maneuvers are not expected under the intended conditions of clinical use. Therefore, the results demonstrate acceptable torque strength.
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.
Tip flexibility	Tip Flexibility testing was performed to measure the force required to deflect Tigertriever 13 tips to 90 degrees.	The subject device met acceptance criteria.
Kink resistance	Kink evaluation was performed for the distal section and for the proximal section of the device, in simulated bends representative of the intended clinical anatomy.	Kink resistance was evaluated under conditions simulating anatomic tortuosity and demonstrated acceptable performance.
Tensile test	The minimum force to break the subject device was tested for all joints.	The tensile strength of the device met acceptance criteria based on recognized standards (ISO 10555-1).
Particulates	Particulate test was performed according to the light obscuration test method. Simulated use testing of the subject device was performed in an anatomical model. Devices were flushed and the fluid was evaluated for particle sizes of ≥10, ≥25 and ≥50 µm.	The particulate generated by the subject device was similar to the particulate generated by the predicate device.
Austenite Finish (Af) Temperature	The Active Af temperature was determined from a graph of displacement as a function of temperature (Bend and Free Recovery per ASTM F2082)	The Af temperature of the device met acceptance criteria.

Performance Bench Testing		
Test	**Test Method Summary**	**Conclusions**
Coating integrity assessment	The test was performed with the Comaneci device, as the design of the two devices is the same in terms of the core wire mechanism. Damage to the PTFE core wire coating was evaluated following simulated use.	Results demonstrated no damage to the coating following simulated use.
Corrosion	The test was performed with the Comaneci device and not with the subject device. The device was immersed in saline for 5 hours at room temperature, boiled in distilled water for 30 min, and maintained in 37°C for 48 hours. After the above treatment, device is tested for corrosion.	No corrosion was observed, which meets the acceptance criteria based on recognized standards (ISO 10555-1).

Pre-Clinical Animal Testing Data

The safety of the Tigertriever 13 was assessed in two pre-clinical studies at sub-acute and 30-day (chronic) time points. After procedures, animals were assessed in vivo until their scheduled sub-chronic or chronic timepoints. In each tested vessel three passes were performed, one pass with clot and two passes without clots. The simulation included clots of variable hardness and consistency. Treated vessel diameters ranged from 1.1-3.2mm; this range complies with the target clinical indication of the large intracranial vessel occlusion, which includes vessels size of 1.5 mm and larger. Full reperfusion was demonstrated in all procedures, and there was no evidence of vessel damage (i.e., dissection, perforation, clot formation) related to device deployment. Histopathological assessment of treated vessels was considered acceptable. Tigertriever 13 pre-clinical studies thus demonstrate that the device has acceptable safety and clot retrieval performance.

Conclusion

The Tigertriever 13 Revascularization Device has the same indications for use and principles of operation, and similar technological characteristics as the predicate device. The differences in technological characteristics between the subject and predicate devices do not raise different questions regarding the safety and effectiveness. Non-clinical performance testing as discussed above demonstrates similar performance and safety characteristics between the Tigertriever 13 Revascularization Device and the predicate device, thus supporting the conclusion that the Tigertriever 13 Revascularization Device is substantially equivalent to the predicate device.