March 23, 2021

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

Re: K203592
Trade/Device Name: Tigertriever and Tigertriever 17 Revascularization Device
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NRY
Dated: February 19, 2021
Received: February 19, 2021

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,
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OHT5: Office of Neurological
and Physical Medicine Devices
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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)*
K203592

Device Name
Tigertriever and Tigertriever 17 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
Tigertriever Revascularization Device
K203592

Submission Sponsor

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Date Prepared

March 23, 2021

Device Identification

Trade/Proprietary Name: Tigertriever and Tigertriever 17 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)

Solitaire 2 Revascularization Device (K141491)

Indication 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 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. Two versions of the device are available. The standard version Tigertriever (TRPP7155) has a net length of 32mm (unexpanded form) and it is delivered through a microcatheter with an internal diameter of 0.021 inches. The shorter version Tigertriever 17 (TRPP7166) has a net length of 23 mm (unexpanded form) and it is delivered through a microcatheter with an internal diameter of 0.017 inches. The Tigertriever is provided with a 3.5 Fr peelable loading sheath.

Comparison of Technological Characteristics with the Predicate Device

The Tigertriever and the Solitaire 2 predicate have the same indications for use, similar technological characteristics and principle of operations. Both stentrievers share similar design and similar construction materials. Both devices are used to restore blood flow by removing thrombus from a large intracranial vessel in patients experiencing ischemic stroke. Both stentrievers are delivered to the target vessel by means of a microcatheter and expanded once deployed from the microcatheter. The expansion of the subject device is controlled by the physician, while the predicate mesh is self-expanded to a fixed diameter upon deployment. However, this difference does not raise new questions of safety or effectiveness. A detailed comparison between the Tigertriever and the predicate device is provided in the table below.

	Tigertriever Revascularization Device	**Solitaire 2 Revascularization Device (Predicate Device)**
510(k) Number	K203592	K141491
Regulation	21 CFR 870.1250	21 CFR 870.1250
Product Code	NRY	NRY

	Tigertriever Revascularization Device	Solitaire 2 Revascularization Device (Predicate 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 Solitaire 2 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
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, Tyvek pouch, and Carton box
Distal OD (expanded configuration)	3mm Tigertriever 17 6mm Tigertriever	4mm 6mm
Stent length (unexpanded configuration)	23mm Tigertriever 17 32mm Tigertriever	31mm
Overall length	200 cm	184 cm
Design of distal portion	Close end braided nitinol mesh, manually expandable	Open end laser cut stent, self-expanded
Mode of operation	Manual expansion of the braided distal portion into the clot using the handle component	Self-expansion of the distal stent portion into the clot following retraction of the delivery catheter
Materials		
Stent	Nitinol	Nitinol
Markers	90% Platinum/ 10% Iridium	90% Platinum/ 10% Iridium

	Tigertriever Revascularization Device	Solitaire 2 Revascularization Device (Predicate Device)
Core wire (shaft)	Nitinol core wire and stainless steel shaft	Nitinol wire
Push wire shrink tubing	PTFE	PTFE
Introducer Sheath	PTFE/Grilamid	PTFE

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 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 (Intracutaneous Reactivity), Sensitization, Hemocompatibility, Pyrogenicity, Acute Systemic and Toxicity Testing. In addition, in vivo thrombogenicity was performed for the Tigertriever. Results of the biocompatibility testing indicate that Tigertriever 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 – Intracutaneous 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

Biological Endpoint	Test Results	Conclusion
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
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 is sterilized by 100% Ethylene Oxide.

The shelf life testing for Tigertriever revascularization device has been conducted (T = 2.5 years) with test results confirmed that all acceptance criteria were met.

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.

Performance Bench Testing		
Test	**Test Method Summary**	**Conclusions**
Simulated use test	Simulated use testing of the Tigertriever Revascularization Device was performed in an	The device was tested for handling and clot retrieval in an in vitro tortuous path

Performance Bench Testing		
Test	**Test Method Summary**	**Conclusions**
	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.	anatomical model, which has been used in the evaluation of other similar devices. 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 lumen diameters applicable to the intended vasculature 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 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 other similar devices. 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

Performance Bench Testing		
Test	**Test Method Summary**	**Conclusions**
		of clinical use. Therefore, the results demonstrate acceptable torque strength.
Dimensions test	Dimensional inspection was tested per engineering drawings.	The subject device dimensions are within the range of existing predicate dimensions for this device type. The minor differences in dimensions do not affect performance, safety or effectiveness.
Tip flexibility	Tip Flexibility was performed to measure the force required to deflect Tigertriever tips to 90 degrees at 7mm test lengths.	The subject device met acceptance criteria based on comparable device used in the same anatomy and demonstrated similar tip flexibility.
Kink resistance	Tigertriever with ancillary microcatheter was looped around post of calibrated kink measurement jig (0.25" diameter) about 50mm from the distal end of the microcatheter.	Kink resistance was evaluated under conditions simulating anatomic tortuosity, comparable to predicates, and demonstrated acceptable performance.
Tensile test	The minimum force to break the Tigertriever 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 and predicate devices 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	The Af temperature of the device met acceptance criteria.

Performance Bench Testing		
Test	**Test Method Summary**	**Conclusions**
	temperature (Bend and Free Recovery per ASTM F2082).	
Coating integrity assessment	The test was performed with the Comaneci device and not with the subject device (the design of the two device 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 device was Immersed in saline for 5 hours at RT, then the device is boiled in distilled water for 30 min, and finally device is 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 was demonstrated in a controlled animal study in domestic swine comparing the Tigertriever device and the predicate device. The results of the study showed substantial equivalence between the subject device and the predicate device.

The study included four animals; two animals were used for the acute stage (3 days period) and two animals were used for the chronic stage (30 days period). The study included two procedures: the first procedure was performed on day zero (3 or 30 days before the animal was sacrificed), and the second procedure was performed on the sacrifice day (day 3/day 30).

The first procedure included simulation (both for test device and predicate device) at two sites in the femoral artery, each simulation included three passes, first pass with clot removal, and two additional passes without clot (total three device delivery and retrieval simulations at each site of the femoral artery). No damage was observed by angiography during procedure in the subject device and the predicate device treated sites, no safety related abnormalities were observed by the veterinarian and no abnormal gross findings were recorded for external surface, orifices, cavities, or muscles and tissues downstream of the femoral arteries. In addition, the histology evaluations of the arterial tested sites revealed a comparable range of observations for the subject and predicate devices.

The second procedure was performed on the study termination day before the animal was sacrificed. To evaluate the thrombogenicity of the subject and predicate device, the tested unit was inserted to the renal artery in one side of the kidney and deployed for 10 minutes, then an additional two passes were performed, resulting in a total of 30 minutes for each device. Thrombogenicity scores revealed comparable values for the subject and predicate devices; kidney microscopic and histology evaluations revealed comparable range of observations for the subject and predicate devices.

In conclusion, the animal study showed that thrombectomy using the Tigertriever was safe without evidence of vessel injuries or abnormal thrombogenicity. Clinical, angiographic, pathologic, and histologic data supported a similar safety profile between the Tigertriever and the Solitaire predicate.

Clinical Study

The TIGER (Treatment with Intent to Generate Endovascular Reperfusion) clinical trial assessed the efficacy and safety of the Tigertriever Revascularization Device against a performance goal derived from the TREVO 2, SWIFT, MR CLEAN, ESCAPE, REVASCAT and SWIFT PRIME clinical trials. Key inclusion criteria were: patients with a large-vessel occlusion who could be treated within 8 hours of stroke symptom onset; age 18-85; 8≤NIHSS≤29; angiographic confirmation of an occlusion of an ICA, MCA, M1 or M2, vertebral or basilar arteries, and IV t-PA, if used, was initiated within 3 hrs of stroke onset. Key exclusion criteria were: angiographically evident excessive arterial tortuosity, stenosis, or any occlusion, in a proximal vessel that required treatment or would prevent access to the site of occlusion.

One hundred and sixty (160) patients signed informed consent, treated with the Tigertriever device and included in the study. Of these, 148 patients met all inclusion and exclusion criteria as requested by FDA for the modified Intent-to-Treat (mITT) Cohort. Among the 12 patients excluded to meet the FDA defined mITT criteria, 1 had excessive arterial tortuosity, 2 had prior recent stroke in the past 3 months, 1 had a 100% occluded vessel which required stenting, 2 did not meet the criteria around laboratory ranges, 1 was given IV t-PA initiated >3 hours from symptom onset, 1 was treated with mRS 3, 2 missing pregnancy test, 1 was treated with the device over 8 hours from symptom onset, and 1 was treated with an aspiration device prior to the Tigertriever. Per FDA's request, within this mITT cohort, use of rescue therapy at any point in the procedure was imputed as a failure for the revascularization and clinical outcome endpoints. The table below summarizes the effectiveness and safety outcomes of this cohort.

The Primary Effectiveness Endpoint was successful revascularization defined as an mTICI score of at least 2b in the target vessel, following three or less passes of the Tigertriever device, using Core Laboratory adjudicated data. The Primary Safety Endpoint defined as the composite

of all-cause mortality at 90 days and/or symptomatic intracranial hemorrhage (sICH) within 24 (18-36) hours of the study procedure. The Primary Safety Endpoint was adjudicated by the Clinical Events Committee (CEC).

TIGER Study Results **Effectiveness and Safety Results for use of only Tigertriever**	
Endpoint	**mITT (N=148)**
Successful revascularization rate after Tigertriever treatment[1] - Patients with mTICI ≥2b, n (%)	108/148 (73%)
Lower Bound of 95% CI	66.3%
Secondary Effectiveness Endpoints	
Successful revascularization rate after first pass with Tigertriever - patients with mTICI ≥ 2b	**mITT (N=148)**
n (%)	81 (54.7%)
Good Clinical Outcome: mRS ≤2 at 90 days[2]	**N= 148**
n, (%)	81/148 (54.7%)
Patient Reported Outcomes: EQ5D at 90 days[3]	**N= 107**
Mean (SD)	73.5 (21.8)
Median	80
25th to 75th	62.5,90
Patient Reported Outcomes: ALDS at 90 days[3]	**N= 109**
Mean (SD)	11.1 (4.5)
Median	13.0
25th to 75th	8,15
Primary Composite Safety Endpoint	
Endpoint	**mITT (N=147)[4]**
Mortality at 90 Days and/or sICH at 24 Hours post procedure[4]	26 (17.7%)
Upper Bound of 95% CI	24.8%
Mortality at 90 Days[4]	26 (17.7%)
sICH at 24 Hours post procedure[5]	3 (2.0%)
Secondary Safety Endpoints	
Endpoint	**mITT (N=147)[6]**
Total Asymptomatic ICH at 24 Hours (%), n (%)	47 (31.9%)
HI-1	18 (12.2%)
HI-2	12 (8.8%)
PH-1	0
PH-2	2 (1.4%)
SAH	11 (7.5%)
SAH and HI-2	2 (1.4%)
SAH and PH-2	1 (0.7%)
Neurological Deterioration at 24 Hours, n (%)	13 (8.8%)
Embolization to New Territory at End of Procedure, n (%)	4 (2.7%)

[1] **Use of rescue therapy at any point in the procedure was imputed as a failure to achieve the endpoint. There were 12 cases imputed as failure.**
[2] Five patients had missing 90 days mRS and were imputed as a failure to achieve the endpoint.
[3] Sample sizes vary due to missing data at 90 days.
[4] Reduced sample size due to one patient who withdrew consent prior to the 90 d follow up visit.
[5] All 3 subjects with sICH at 24 hours post-procedure died.
[6] Reduced sample size due to missing 24 hour CT or final angiogram.

Definitions:

mRS: modified Rankin Score.
EQ5D: EuroQol Five Dimensions.
ALDS: Academic Medical Center Linear Disability Score.
sICH: symptomatic Intracranial Hemorrhage, any parenchymal hematoma type 2, remote intracerebral hemorrhage, subarachnoid hemorrhage, or intraventricular hemorrhage that is the predominant cause of ≥4 points NIHSS deterioration at 24 hours.
HI: Hemorrhagic Infarction.
PH: Parenchymal Hematoma.
SAH: Subarachnoid Hemorrhage.

TIGER Summary of Serious Adverse Events (SAEs)

One hundred and sixty-five (165) SAE occurred within all the study population, all patients enrolled and treated with Tigertriever. The table below summarizes the frequency of the SAEs classified by System Organ.

System Organ Class (SOC)	All (165 Events)
Blood and lymphatic system disorders	3 (1.8%)
Cardiac disorders	22 (13.3%)
Gastrointestinal disorders	6 (3.6%)
General disorders and administration site conditions	2 (1.2%)
Infections and infestations	11 (6.7%)
Injury, poisoning and procedural complications	12 (7.3%)
Injury, poisoning and procedural complications|Vascular disorders	1 (0.6%)
Investigations	3 (1.8%)
Metabolism and nutrition disorders	3 (1.8%)
Musculoskeletal and connective tissue disorders|Psychiatric disorders	1 (0.6%)
Nervous system disorders	40 (24.2%)
Nervous system disorders|Injury, poisoning and procedural complications	1 (0.6%)
Nervous system disorders|Nervous system disorders	1 (0.6%)
Nervous system disorders|Surgical and medical procedures	1 (0.6%)
Psychiatric disorders	1 (0.6%)
Renal and urinary disorders	4 (2.4%)
Reproductive system and breast disorders	1 (0.6%)

System Organ Class (SOC)	All (165 Events)
Respiratory, thoracic and mediastinal disorders	25 (15.2%)
Skin and subcutaneous tissue disorders	1 (0.6%)
Surgical and medical procedures	2 (1.2%)
Vascular disorders	24 (14.5%)

To conclude, the TIGER study was successfully met all pre-defined success criteria. Based on the results of this clinical study, the Tigertriever device, when used for the revascularization in ischemic stroke due to LVOs, has reperfusion rates and a safety profile similar to alternative devices. Therefore, the clinical data support the substantial equivalence.

Statement of Substantial Equivalence

The Tigertriever device has the same intended use and indications for use, and similar technological characteristics compared to the Solitaire 2 predicate device. The differences in technological characteristics between the Tigertriever and the predicate device were evaluated in bench, animal and clinical testing as discussed above and do not raise different questions regarding the safety and effectiveness and demonstrate similar performance and safety characteristics between the Tigertriever and predicate device. Therefore, the results from these tests support the conclusion that the Tigertriever device is substantially equivalent to the predicate device.