DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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February 5, 2015

Micro Therapeutics, Inc., d/b/a ev3 Neurovascular
Mr. Larry Boucher
Senior Regulatory Affairs Specialist
9775 Toledo Way
Irvine, California 92618

Re: K141516
Trade/Device Name: MindFrame Capture™ LP Revascularization Device
Regulation Number: 21 CFR 870.1250
Regulation Name: Catheter, Thrombus Retriever
Regulatory Class: Class II
Product Code: NRY
Dated: December 24, 2014
Received: January 5, 2015

Dear Mr. Boucher,

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141516

Device Name
Capture™ LP Revascularization Device

Indications for Use *(Describe)*
The Capture™ LP 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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1. 510(k) Summary

510(k) Owner:	Micro Therapeutics, Inc. d/b/a ev3 Neurovascular 9775 Toledo Way Irvine, CA 92618 Establishment Registration No. 2029214
Contact Person:	Larry Boucher Senior Regulatory Affairs Specialist Telephone: (949) 297-9781 E-mail: larry.boucher@covidien.com
Date Summary Prepared:	28 January 2015
Trade Name of Device:	Capture™ LP Revascularization Device
Common Name of Device:	Catheter, Thrombus Retriever
Classification of Device:	21 CFR 870.1250 – Class II
Predicate Device:	Solitaire™ FR Revascularization Device 510(k)#: K113455
Performance Data:	The following bench testing was performed in support of the Capture™ LP Revascularization Device:

- A_f Temperature Testing
- Radial Force Testing
- Radiopacity Testing
- Kink Resistance Testing
- Dimensional Testing
- Durability Testing
- Delivery Force Testing
- Re-sheathing (withdrawal) Force Testing
- Component and Attachment (Tensile) Integrity Testing
- Torque Strength Testing
- Performance (Clot Retrieval) Testing
- Physician Usability Testing

	Biocompatibility testing, sterilization validation, and a 2-year accelerated aging study were also performed. In addition, an acute and 30-day and 90-day chronic animal studies were performed.
Conclusion:	The Capture™ LP device is substantially equivalent to the Solitaire™ FR device based on the successful completion of non-clinical bench and animal testing as well as similar principles of design, operation and indications for use.

Device Description:

The Capture™ LP device is designed to restore blood flow in patients experiencing ischemic stroke due to large intracranial vessel occlusion within 8 hours of symptoms onset. It is indicated for subjects who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy. The distal nitinol portion of the device facilitates clot retrieval and has Platinum -Iridium and Platinum-Tungsten radiopaque markers on the proximal and distal ends respectively. The device is supplied sterile and is intended for single-use only by physicians trained in interventional neuroradiology and treatment of ischemic stroke.

Indications for Use:

The ev3 / Covidien Capture™ LP 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 Comparison

The table below provides a comparison of the technological characteristics of the Capture™ LP Revascularization Device and the Solitaire™ FR Revascularization Device.

Characteristic	Solitaire™ FR	Capture™ LP	Rationale for Difference (If Present)
Indication for Use	The Solitaire™ FR 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 Capture™ LP 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.	N/A

Characteristic	Solitaire™ FR	Capture™ LP	Rationale for Difference (If Present)
Sizes Offered	4x15mm 4x20mm 6x20mm 6x30mm	3x20mm 3x30mm 4x20mm 4x30mm	The Capture™ LP device is designed to be delivered through a smaller ID (0.432 mm/0.017" inner diameter) micro catheter.
Device Design	Laser-cut stent attached to a nitinol push-wire	Laser-cut stent attached to a nitinol push-wire	N/A
Distal End Design	"Overlapping" design	Tubular design	The results of bench testing and animal testing establish the equivalency of the Capture™ LP device and the Solitaire™ FR device.
Materials			
Stent	Nitinol	Nitinol	N/A
Distal Marker	90% Platinum/ 10% Iridium	92% Platinum/ 8% Tungsten	The material used for the Capture™ LP device was shown to be biocompatible per ISO 10993 testing. In addition, the Radiopacity of the material was shown to be equivalent to that of the Solitaire™ FR device through design verification testing.
Proximal Marker	90% Platinum/ 10% Iridium	90% Platinum/ 10% Iridium	N/A
Tip Attachment	Mechanical/Dymax adhesive	Laser welded	The tensile strength of the attachment zone was shown to be equivalent to Solitaire™ FR through design verification testing.
Marker Attachment	Laser weld	Solder (Gold/Tin)	The material used for the Capture™ LP device was shown to be biocompatible per ISO 10993 testing. In addition, the tensile strength of the marker attachment was shown to be equivalent to that of the Solitaire™ FR device through design verification testing.
Pusher Wire	Nitinol	Nitinol	N/A
Introduction Sheath	PTFE	HDPE	The material used for the Capture™ LP device was shown to be biocompatible per ISO 10993 testing.

Sterilization and Shelf Life

The packaged Capture™ LP Revascularization device will be sterilized using a validated gamma irradiation sterilization cycle. The sterilization cycle has been validated to ensure a sterility assurance level (SAL) of 10^{-6} in accordance with ISO 11137-1/-2, Sterilization of health care products – Radiation sterilization – Substantiation of 25 kGy as a sterilization dose – Method VDmax25.

Aging studies for the Capture™ LP Revascularization Device have established the product and packaging remain functional and maintain sterility for up to 2 years. Aging studies for packaging integrity (per ASTM F2096-11), seal strength and device functionality were performed and met all acceptance criteria.

Biocompatibility

Biocompatibility testing for the Capture™ LP Revascularization Device was conducted to conform with FDA consensus standard, recognition number 2-156, AAMI/ANSI/ISO 10993-1:2009, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process. The table below summarizes the biocompatibility testing performed on the Capture™ LP device.

Test	Result	Conclusion
Cytotoxicity – L929 MEM Elution	The test article scored a "0" (no cytotoxic reaction) at 24, 48, and 72±4 hours	Non -cytotoxic
Klingman Maximization Test	No animal challenged with the test article extracts were observed with a sensitization response greater than "0."	Non-sensitizer
Intracutaneous Injection Test	The differences between the mean test and control scores of the extract dermal observations were less than 1.0	Non-irritant
Acute Systemic Injection Test – ISO	None of the animals injected with the test article extract show a significantly greater biological reaction than animals treated with the control extract vehicle.	Not systemically toxic
Rabbit Pyrogen Test	The difference between the individual rabbit's maximum temperature and baseline temperature was ≤0.5°C.	Non-pyrogenic
Complement Activation C3a and SC5b-9	Test article and control devices exhibited similar activation respective of the normalized C3a and SC5b concentration produced by CVF	Levels of the compliments C3a and SC5b complements were similar for Capture LP and control device
Hemolysis: Direct Contact/Extract	The blood had a plasma free hemoglobin level of 0.9455 mg/ml.	Non-hemolytic
In Vitro Hemocompatibility/ Platelet and Leukocyte	The mean of the three readings for the reference material, negative control, comparison and test articles were within	No adverse effect on platelet and leukocyte counts

Test	Result	Conclusion
Count	±25% of the respective average values	
Partial Thromboplastin Time	The mean clotting time values for the test article were 90% of the negative control.	No adverse effect on prothrombin coagulation time of human plasma.
Thrombosis (In Vivo) – 2 dog	Implantation of the test and control devices in the jugular veins resulted in no adverse effects or clinical signs	The Capture LP device and control device have similar thromboresistance characteristics
Reverse Mutation Assay (Ames)	None of the tester strains shoes an increase in reversion rates when treated with the test article	Non-mutagenic
In Vitro Mouse Lymphoma Assay with Extended Treatment	The mutant frequencies and cloning efficiencies of preparations treated with the test article were within the limits defined for a negative response.	Non-mutagenic
In Vivo Mouse Micronucleus Assay	There were no biologically significant increases in mPCE production in the test article treated groups.	Non-mutagenic

Performance Data – Bench

A summary of the pre-clinical bench testing performed for the Capture™ LP Revascularization device is presented in the table below.

Test	Method	Conclusions
Total Length	The total length of the device was measured from distal tip to proximal wire	All devices met acceptance criteria.
Delivery and Re-sheathing Force Testing	Delivery and re-sheathing force were tested during simulated use in a representative tortuous anatomical model	Delivery and re-sheathing force testing met acceptance criteria. Delivery and re-sheathing force same as predicate.
Durability Testing	Device was evaluated for delivery and withdrawal beyond the recommended number of passes and re-sheathings recommended in the IFU.	Devices demonstrated no damage after delivery and withdrawal. Durability same as predicate.
Differential Scanning Calorimetry (DSC) Testing	A_f Temperature measured using DSC testing per ASTM F2004-05	The transformational temperature is lowered as the size of the device increases.
Kink Resistance Testing	Device was delivered through a bend in a fixture of known radius and then inspected in-place for any kinks or poor wall apposition.	Device was resistant to kinking around small radii turns. Kink radii smaller than predicate due to smaller device size.
System Tensile Testing	Fully assembled devices were tested to failure and peak tensile strength recorded.	System tensile testing met acceptance criteria. System tensile strength same as predicate.
Markercoil Tensile Strength Testing	Device was tested to determine the tensile strength of the bonds of the distal radiopaque markers	The tensile strength of the distal radiopaque markers met acceptance criteria. The markercoil tensile strength same as predicate.
Torque Strength Testing	Device was torqued in a representative tortuous model to determine number of rotations to separate device	Torque strength testing met acceptance criteria. Torque strength same as predicate.

Test	Method	Conclusions
Radial Force Testing	Radial force testing performed on device within recommended vessel diameters specified in IFU.	Radial force testing of the Capture™ LP device is comparable to the predicate device for the recommended vessel diameters specified in IFU.
Radiopacity	Angiography of device taken in porcine model.	Radiopacity of Capture™ LP device equivalent to that of the predicate device.
Performance Test (Clot Retrieval Bench Test)	Device was delivered through a tortuous anatomical model to evaluate the effectiveness of the device to retrieve soft and hard clots of various lengths and diameters	Capture™ LP device restored distal blood flow 100% of the time. Performance testing better than predicate device.
Physician Usability Testing	The device was delivered in a tortuous benchtop model to assess the users' ability reliably deploy and use the neurothrombectomy device.	Capture™ LP rated similar to the predicate device when used with the Rebar-14 microcatheter.

Performance Data – Animal

An acute animal study was performed that assessed usability, effectiveness, and safety of the Capture™ LP device as compared to the predicate device. A total of six swine were evaluated for usability effectiveness and safety. Effectiveness was measured by placing manufactured clot in the animal pharyngeal artery and assessing the ability of the device to retrieve the clot and restore blood flow to the target vessel. Safety was assessed by passing the device multiple times through the chose vessel and conducting an angiographic and histopathological evaluation. A summary of the study results is presented in the table below.

Test	Result	Conclusion
Successful Clot Retrieval	The device was deployed to retrieve manufactured clot in the pharyngeal artery of porcine model.	The Capture™ LP device was able to retrieve the manufactured clot in all test animals. Clot recovery is the same as the predicate device.
Sustained Flow (TIMI 2 or 3) In Clot Vessel	After clot retrieval, blood flow to the target vessel and distal vasculature was assessed.	Blood flow was assessed with a TIMI score of 2 or 3 for all vessels where the Capture™ LP device was used to retrieve clot. Blood flow restoration the same as that for the predicate device.

Average Number of Passes for Clot Retrieval	The number of passes to successfully retrieve clot was evaluated.	The number of passes for the Capture™ LP to successfully retrieve clot from the target vessels is equivalent to that of the predicate device.

The histological findings observed for both the Capture™ LP and the predicate devices demonstrated that the artery response to neurothrombectomy was comparable between the two devices.

30-day and 90-day chronic animal studies were performed to evaluate the usability and safety of the Capture™ LP device. In each study, the device was deployed and recovered in the vasculature of the swine test subjects and angiographic and histopathologic assessments were performed for vessel damage, thrombus formation, and vasospasm. Angiographic visualization during the procedure and just prior to subject sacrifice demonstrated that there was no wall damage or thrombus formation during the treatment. Histopathologic evaluation demonstrated that the artery response to the neurothrombectomy procedure was considered to be comparable between the Capture™ LP device and the predicate device.

Performance Testing – Clinical

Substantial equivalence of the Capture™ LP Revascularization Device has been established to the predicate device through the results of bench and animal testing. Equivalence has also been established through an evaluation of the indications for use, performance specifications, packaging, and the fundamental scientific technology. Therefore, clinical data is not required for the Capture™ LP device.