



Food and Drug Administration
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December 23, 2015

Micro Therapeutics, Inc. d/b/a ev3 Neurovascular
Ms. Phuong Chau
Senior Regulatory Affairs Product Specialist
9775 Toledo Way
Irvine, California 92618

Re: K153071

Trade/Device Name: Solitaire™ Platinum Revascularization Device
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NRY
Dated: November 23, 2015
Received: November 25, 2015

Dear Ms. Phuong Chau:

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,

William J. Heetderks -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K153071

Device Name

Solitaire™ Platinum Revascularization Device

Indications for Use (Describe)

The Solitaire™ Platinum 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.

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510(k) Summary K153071

510(k) Owner: Micro Therapeutics, Inc. d/b/a ev3 Neurovascular
9775 Toledo Way
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Establishment Registration No. 2029214

Contact Person: Phuong Chau
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Date Summary Prepared: December 14, 2015

Trade Name of Device: Solitaire™ Platinum Revascularization Device

Common Name of Device: Catheter, Thrombus Retriever

Classification of Device: 21 CFR 870.1250 – Class II

Product Code NRY

Predicate Device: Solitaire™ 2 Revascularization Device
510(k)#: K123378 and K141491
Solitaire™ FR Revascularization Device (Biocompatibility)
510(k)#: K113455

Performance Data: The following bench testing was performed in support of the Solitaire™ Platinum device:

- Delivery Force Testing
- Re-sheathing Force Testing
- Multiple Re-sheathing Durability
- Body Finger Marker Tensile
- Body Markers Radiopacity
- Radial Force (in-process)

The following test data was adopted from the predicate device:

- Total System Length
- Kink Resistance
- Total System Tensile
- Distal Marker Coil Tensile

- Clot Retrieval Bench and Device Recovery Durability
- Torque Response
- Torque Strength
- Radiopacity (Distal Markers)
- Fluorosafe Marker Location

Biocompatibility, sterilization, and aging data were also adopted from the predicate device as there is no change to the materials of construction, design, manufacturing process, or packaging for the addition of this additional model.

An animal study to assess usability was performed. No animal testing for safety and efficacy or clinical studies were performed as there is no change to the indications for use or the fundamental scientific technology of the device.

Conclusion: The Solitaire™ Platinum device is substantially equivalent to the currently cleared Solitaire™ 2 and Solitaire™ FR device based on the completion of non-clinical bench testing and animal usability testing as well as similar principles of design, operation and indications for use.

Device Description:

The Solitaire™ Platinum device is designed to restore blood flow in patients experiencing ischemic stroke due to large intracranial vessel occlusion. The device is designed for use in the neurovasculature such as the internal carotid artery, M1 and M2 segments of the middle cerebral artery, basilar, and the vertebral arteries. The distal nitinol portion of the device facilitates clot retrieval and has Pt-Ir radiopaque markers on the working cell length, proximal and distal ends. The Solitaire™ Platinum device is a modification to the currently cleared Solitaire™ 2 Revascularization Device to increase the working length radiopacity.

Indication for Use:

The Solitaire™ Platinum 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 Solitaire™ Platinum device and the currently cleared Solitaire™ 2 Revascularization Device.

	Solitaire FR (K113455)	Solitaire™ 2 (K123378 & K141491)	Solitaire™ Platinum	Rationale for Difference (if present)
Indication for Use	The Solitaire™ FR Revascularization	The Solitaire™ 2 Revascularization	Same	N/A

	Solitaire FR (K113455)	Solitaire™ 2 (K123378 & K141491)	Solitaire™ Platinum	Rationale for Difference (if present)
	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 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.		
Method of Supply	Stored within dispenser coil, Tyvek pouch, & shipping carton	Stored within dispenser coil, Tyvek pouch, & shipping carton	Same	N/A
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Same	N/A
Device Sizes	4x15mm 4x20mm 6x20mm 6x30mm	4x15mm 4x20mm 4x40mm 6x20mm 6x30mm	4x20mm 4x40mm 6x20mm	The three sizes are within the range of sizes cleared for Solitaire 2 and Solitaire FR.
Materials				
Stent	Nitinol	Nitinol	Same	N/A
Push-wire	Nitinol	Nitinol	Same	N/A
Distal Marker Coils	90% Platinum/ 10% Iridium	90% Platinum/ 10% Iridium	Same	N/A
Body Marker Fingers & Coils	N/A	N/A	90% Platinum/ 10% Iridium Same material as Distal Marker Coils as predicate.	Markers are added to the body of the stent retriever to increase radiopacity. Bench testing has demonstrated that this change does not raise new question on the safety and effectiveness of the device.
Push-wire	PTFE	PTFE	Same	N/A

	Solitaire FR (K113455)	Solitaire™ 2 (K123378 & K141491)	Solitaire™ Platinum	Rationale for Difference (if present)
Shrink Tubing				
Introducer Sheath	PTFE/Grilamid	PTFE/Grilamid	Same	N/A

Sterilization and Shelf Life

The packaged Solitaire™ Platinum device will be sterilized using a validated Ethylene Oxide sterilization cycle. The materials of construction, design, manufacturing process, and packaging are identical to the predicate device. Therefore no additional validation testing is required.

Aging studies for the Solitaire™ 2 Revascularization Device have established the product and packaging remain functional and maintain sterility for up to 2 years. Aging studies for packaging integrity, seal strength and device functionality were performed and met all acceptance criteria. The materials of construction, design, manufacturing process, and packaging of the Solitaire™ Platinum device are identical to the predicate device. Therefore the existing aging and packaging data has been adopted for the Solitaire™ Platinum.

Biocompatibility

Biocompatibility data for the Solitaire device family was tested for the Solitaire™ FR Revascularization Device. The biocompatibility data for the Solitaire™ FR was adopted for the Solitaire™ 2 Revascularization Device. The Solitaire™ Platinum does not introduce any new materials into the finished device or the manufacturing process. Therefore the existing biocompatibility testing data has been adopted for the Solitaire™ Platinum.

Performance Data – Bench

A summary of the bench testing performed for the Solitaire™ Platinum is summarized in the table below.

Test	Method	Conclusion
Delivery Force	Peak delivery force was measured through a representative tortuous anatomical model.	All devices met acceptance criteria.
Re-sheathing Force	Retrieval force was measured through a representative tortuous anatomical model.	All devices met acceptance criteria.

Test	Method	Conclusion
Multiple Re-sheathing Durability	Samples were evaluated on their ability to withstand delivery and withdrawal forces in a representative tortuous model beyond the recommended number of passes and re-sheathings allowed per the IFU	All devices showed no irregularities, breaks, kinks, marker coil migration, glue separations, or other observed defects after all attempts. All devices met acceptance criteria.
Body Finger Marker Tensile	Markercoil tensile strength testing is performed to verify the strength of the laser weld of the Pt/Ir markercoil to the Nitinol distal finger of the device.	All devices met acceptance criteria.
Radial Force	The radial force was measured 100% in-process.	Radial force was measured 100% in-process on test builds. All devices met acceptance criteria.
Body Markers Radiopacity	Verification analysis of body markers.	All devices met acceptance criteria.

Performance Data – Animal

Animal usability testing was performed and assessed by an interventional neurologist on the following attributes after each pass: delivery of the device through the microcatheter, the ability to deploy the retriever, the ability to resheath and redeploy the retriever, the ability to retrieve the device through the guide catheter, the device condition, and the fluoroscopic visibility of the radiopaque body markers.

Performance Testing – Clinical

No clinical study was performed as there is no change to the indications for use or the fundamental scientific technology for the new model number.