December 21, 2017

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

Re: K172448
Trade/Device Name: Riptide™ Aspiration System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NRY
Dated: November 20, 2017
Received: November 21, 2017

Dear Mr. Ryan Kenney:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172448

Device Name
Riptide™ Aspiration System

Indications for Use *(Describe)*
The Riptide™ Aspiration System is intended for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral – M1 and M2 segments, basilar, and vertebral arteries) 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: K172448

510(k) Owner:	Micro Therapeutics, Inc. d/b/a ev3 Neurovascular 9775 Toledo Way Irvine, CA 92618 Establishment Registration No.: 2029214
Contact Person:	Ryan Kenney Senior Regulatory Affairs Specialist Telephone: (949) 297-5489 Email: ryan.j.kenney@medtronic.com

Date Summary Prepared:	December 18, 2017
Trade Name of Device:	Riptide™ Aspiration System
Common Name of Device:	Catheter, Thrombus Retriever
Regulation Description:	Percutaneous Catheter
Review Panel:	Neurology
Product Code:	NRY
Regulation Number:	21 CFR 870.1250
Device Classification:	Class II
Predicate Device(s):	Penumbra System® and Penumbra Pump MAX™ 510(k)#: K160449
Reference Device(s):	Arc™ Intracranial Support Catheter 510(k)#: K150107 Penumbra System®/Penumbra System MAX™ 510(k)#: K133317 Penumbra Pump MAX™ 510(k)#: K122756 Penumbra Reperfusion Catheter 054 510(k)#: K090752

Device Description:
The Riptide™ Aspiration System is designed to restore blood flow in patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease. The Riptide™ Aspiration System is designed for use within the internal carotid, middle cerebral – M1 and M2 segments, basilar, and vertebral arteries. The Riptide™ Aspiration System is composed of the following components:

- Arc™ Catheter
- Riptide™ Aspiration Tubing
- Riptide™ Aspiration Pump
- Riptide™ Collection Canister with Intermediate Tubing

The Arc™ Catheter is introduced into the vasculature through the Split-Y Introducer Sheath. A lubricous, tapered liner is used to create a structure that has both proximal stiffness and distal flexibility. The Arc™ Catheter has a radiopaque marker band encapsulated at the distal tip for visualization under fluoroscopy. The Arc™ Catheter is navigated to the intended treatment site and positioned proximal to the site of occlusion. The Arc™ Catheter is the only component of the Riptide™ Aspiration System that is used intravascularly.

The Riptide™ Aspiration Tubing serves as a conduit to supply vacuum from the Riptide™ Aspiration Pump to the distal tip of the Arc™ Catheter. The Riptide™ Aspiration Tubing provides a connection between the sterile and non-sterile environments. The proximal end of the Riptide™ Aspiration Tubing is connected to the Riptide™ Collection Canister (outside of the sterile environment) while the distal end of the Riptide™ Aspiration Tubing is connected to the Arc™ Catheter (inside the sterile environment). The Riptide™ Collection Canister is connected to the Riptide™ Aspiration Pump (also outside of the sterile environment) via the Intermediate Tubing.

The Riptide™ Aspiration Pump is designed to generate vacuum for the Riptide™ Aspiration System. The vacuum pressure of the Riptide™ Aspiration Pump is set by turning the vacuum control valve until the vacuum gauge reads a minimum of 20inHg but not exceeding 25inHg. The Riptide™ Aspiration Pump is reusable, non-sterile, and intended to be utilized outside of the sterile environment.

The Riptide™ Collection Canister is provided non-sterile and is pre-assembled with the Intermediate Tubing. The Riptide™ Collection Canister with Intermediate Tubing is single-use and the repository for aspirated material. The Riptide™ Collection Canister is placed into the receptacle of the Riptide™ Aspiration Pump while the Intermediate Tubing is connected to the vacuum inlet port.

Indications for Use:
The Riptide™ Aspiration System is intended for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral – M1 and M2 segments, basilar, and vertebral arteries) 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:

	Predicate Penumbra System® and Penumbra Pump MAX™ (K160449)	Subject Riptide™ Aspiration System
Indication for Use (IFU) Statement	Reperfusion Catheters and Separators: As part of the Penumbra System®, the Reperfusion Catheters and Separators are indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral – M1 and M2	The Riptide™ Aspiration System is intended for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral – M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset. Patients who are ineligible for

	Predicate Penumbra System® and Penumbra Pump MAX™ (K160449)	Subject Riptide™ Aspiration System
	segments, basilar, and vertebral arteries) within 8 hours of symptom onset. <u>Penumbra Aspiration Tubing</u>: As part of the Penumbra System®, the Penumbra Sterile Aspiration Tubing is indicated to connect the Penumbra Reperfusion Catheters to the Penumbra Pump MAX™. <u>Penumbra Pump MAX™</u>: The Penumbra Pump MAX™ is indicated as a vacuum source for Penumbra Aspiration Systems.	intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.
	5MAX™ ACE Reperfusion Catheter	Arc™ Catheter
Materials	Biocompatible, commonly utilized for interventional devices.	Same
Coating	Hydrophilic	Same
Markerband	Radiopaque	Same
Guidewire Compatible	Yes	Same
Dimensions		
Usable Length	132cm	132-135cm
Proximal Inner Diameter	0.068”	0.069”
Proximal Outer Diameter	0.083”	0.0825”
Distal Inner Diameter	0.060”	0.061”
Distal Outer Diameter	0.074”	0.071”
Sterilization		
Method	Ethylene Oxide (EO)	Same
Packaging		
Pouch	Polyethylene	Nylon-Tyvek®
Packaging Hoop	Polyethylene	Same
Packaging Card	Polyethylene	Same
Carton	Solid Bleached Sulfate (SBS) Paperboard	Same
Shelf Life	36 Months	Same
	Penumbra MAX™ Aspiration Tubing	Riptide™ Aspiration Tubing
Materials	Biocompatible, commonly utilized	Same

	Predicate Penumbra System® and Penumbra Pump MAX™ (K160449)	Subject Riptide™ Aspiration System
	for interventional devices.	
Dimensions		
Usable Length	112.0”	Same
Distal Length	7.0”	Same
Inner Diameter	0.088”	Same
Outer Diameter	0.188”	Same
Sterilization		
Method	Ethylene Oxide (EO)	Same
Packaging		
Shelf Life	36 Months	3 Months
	Penumbra Pump MAX™	Riptide™ Aspiration Pump
Performance Characteristics		
Vacuum Range	0-29 inHg (0-98.2 kPa)	Same
Flow Rate	0-0.8 SCFM (0-23 LPM)	Same
Dimensions		
Length	15.5”	16.1”
Depth	11.2”	13.2”
Height	13.2”	12.3”
Weight	22.3lbs	23.6lbs
Electrical Requirements		
Voltage	100-115 Vac	110-115 Vac
Frequency	50 Hz/60 Hz	60 Hz
Duty Cycle	Non-continuous 97.8% (45 minutes on, 1 minute off)	Non-continuous 97% (58.2 minutes on, 1.8 minutes off)
IEC 60601-1 Compliance	Yes	Same
IEC 60601-1-2 Compliance	Yes	Same
	Penumbra MAX™ Canister	Riptide™ Collection Canister with Intermediate Tubing
Dimensions		
Volume	1000mL	1200mL

Biocompatibility:
Biocompatibility was performed for the Arc™ Catheter and the Riptide™ Aspiration Tubing. The Arc™ Catheter is categorized as a limited exposure (< 24 hours), external communicating device contacting circulating blood. The Riptide™ Aspiration Tubing is categorized, for worst-case, as a limited exposure (< 24 hours), external communicating device with indirect blood path contact.

Arc™ Catheter		
Test Description	Results	Conclusions
USP Physiochemical	Meets USP Physicochemical	Pass.

Arc™ Catheter		
Test Description	Results	Conclusions
	extraction parameters	
ISO MEM Elution Using L-929 Mouse Fibroblast Cells	The test article scored '0' at 24, 48 and 72 ± 4 hours and is considered non-cytotoxic under the conditions of this test.	Non-cytotoxic.
ISO Guinea Pig Maximization Sensitization Test	Under the conditions of this protocol, the test article did not elicit a sensitization response.	Non-sensitizer.
ISO Intracutaneous Irritation Test	The differences in the mean test and control scores of the extract dermal observations were < 1.0, indicating that the requirements of the ISO Intracutaneous Reactivity Test have been met by the test article.	Non-irritant.
ISO Acute Systemic Injection Test	None of the test article extract treated animals were observed with clinical signs consistent with toxicity at any of the observation periods.	Non-cytotoxic.
ISO Materials Mediated Rabbit Pyrogen	This response did not exceed the USP limit and meets the requirements for this test. Therefore, these results indicate that the test article was determined to be non-pyrogenic.	Non-pyrogenic.
ASTM Hemolysis Assay – Direct Contact and Extract Method	There were no significant differences between the test article extract and negative control article results. The test article is considered non-hemolytic.	Non-hemolytic.
Complement activation C3a and SC5b-9 Assay	The levels of C3a and SC5b-9 of the test article are comparable to the comparison article and less than that of the positive control.	The compliment activation of the C3a and SC5b assays were similar for test and comparison articles.
Thromboresistance Evaluation	The thromboresistance properties of the Arc™ Catheter are acceptable in clinical use.	The test and control articles exhibited similar thromboresistant characteristics.
ISO Bacterial Mutagenicity Test – Ames Assay	Based on the criteria and conditions of the study	Non-mutagenic.

Arc™ Catheter		
Test Description	Results	Conclusions
	protocol, the test article is considered non-mutagenic.	
ISO *in vitro* Mouse Lymphoma with Extended Treatment	The test article is considered to be non-mutagenic (non-genotoxic and non-clastogenic) in this test system.	Non-mutagenic.
ISO *in vivo* Mouse Micronucleus Assay	Based on the criteria of the assay, the test article is considered non-mutagenic in this test system.	Non-mutagenic.
Partial Thromboplastin Time	Clotting times for Arc™ Catheter were similar to the negative control and the reference material (HDPE), indicating that the device materials are not an activator of the intrinsic coagulation pathway.	Non-activator.
in vitro Hemocompatibility Assay	The Arc™ Catheter did not result in a decrease in any blood component as compared to the reference material. These results indicate that the cause of thrombi is not related to the materials exposed to human blood during use.	No adverse effect on leukocyte or platelet counts.

Riptide™ Aspiration Tubing		
Test Description	Results	Conclusions
ISO MEM Elution Using L-929 Mouse Fibroblast Cells	The test article scored '0' at 24, 48 and 72 $\pm$ 4 hours and is considered non-cytotoxic under the conditions of this test.	Non-cytotoxic.
ISO Guinea Pig Maximization Sensitization Test	Under the conditions of this protocol, the test article did not elicit a sensitization response.	Non-sensitizer.
ISO Intracutaneous Irritation Test	The differences in the mean test and control scores of the extract dermal observations were < 1.0, indicating that the requirements of the ISO Intracutaneous Reactivity Test have been met by the test article.	Non-irritant.
ISO Acute Systemic Injection	None of the test article extract	Non-cytotoxic.

Riptide™ Aspiration Tubing		
Test Description	Results	Conclusions
Test	treated animals were observed with clinical signs consistent with toxicity at any of the observation periods.	
ASTM Hemolysis Assay - Extract Method	Based on the criteria set forth in the protocol, the assay was valid. Therefore, it was capable of correctly assessing the hemolytic potential for test articles. In this case, the test article is considered non-hemolytic under the test conditions employed.	Non-hemolytic.
ISO Materials Mediated Rabbit Pyrogen	This response did not exceed the USP limit and meets the requirements for this test. Therefore, these results indicate that the test article was determined to be non-pyrogenic.	Non-pyrogenic.

The Arc™ Catheter and the Riptide™ Aspiration Tubing have been evaluated to meet requirements specified in ISO 10993-1.

Performance Data – Bench:
Non-clinical bench testing was performed for each component of the Riptide™ Aspiration System. Non-clinical bench testing was performed to evaluate the performance of the design modifications incorporated into the Riptide™ Aspiration System.

The following non-clinical bench testing was performed for the Arc™ Catheter:

Arc™ Catheter		
Test	Test Method Summary	Results
Microbial		
Ethylene Oxide (EO) Residual	EO Residual for the Arc™ Catheter is performed per ISO 10993-7.	The Arc™ Catheter met the acceptance criteria for EO Residual.
Ethylene Chlorohydrin (ECH)	ECH for the Arc™ Catheter is performed per ISO 10993-7.	The Arc™ Catheter met the acceptance criteria for ECH.
Bioburden	Bacterial Endotoxin for the Arc™ Catheter is performed per ANSI/AAMI ST72 and USP 161.	The Arc™ Catheter met the acceptance criteria for Bacterial Endotoxin.
Packaging		

Arc™ Catheter		
Test	Test Method Summary	Results
Visual Inspection	Visual Inspection for the Arc™ Catheter is performed per ASTM F1886.	The Arc™ Catheter met the acceptance criteria for Visual Inspection.
Bubble Leak	Bubble Leak for the Arc™ Catheter is performed per ASTM F2096.	The Arc™ Catheter met the acceptance criteria for Bubble Leak.
Seal Strength	Seal Strength for the Arc™ Catheter is performed per ASTM F88.	The Arc™ Catheter met the acceptance criteria for Seal Strength.
Performance		
Lumen Patency	The proximal hub to the distal tip of the Arc™ Catheter must pass through a stainless-steel mandrel of required size.	The Arc™ Catheter met the acceptance criteria for Lumen Patency.
Dimensional Inspection	The usable length, proximal and distal inner and outer diameter of the Arc™ Catheter is recorded.	The Arc™ Catheter met the acceptance criteria for Dimensional Inspection.
Tip Buckling	The repeated distal tip buckling force under compressive load is evaluated for stiffness.	The Arc™ Catheter met the acceptance criteria for Tip Buckling.
Injection Flow Rate	Injection Flow Rate for the Arc™ Catheter is performed per ISO 10555-1, Annex E with injection through the proximal hub.	The Arc™ Catheter met the acceptance criteria for Injection Flow Rate.
Suction Flow Rate	Suction Flow Rate for the Arc™ Catheter is performed per ISO 10555-1, Annex E with injection through the distal tip.	The Arc™ Catheter met the acceptance criteria for Suction Flow Rate.
Vacuum Resistance	Vacuum Resistance for the Arc™ Catheter is performed under static conditions using a 60cc syringe.	The Arc™ Catheter met the acceptance criteria for Vacuum Resistance.
Air Aspiration Leak	Air Aspiration Leak for the Arc™ Catheter is performed per ISO 10555-1, Annex D.	The Arc™ Catheter met the acceptance criteria for Air Aspiration Leak.
Hub/Shaft Peak Tensile Force	Hub/Shaft Peak Tensile Force for the Arc™ Catheter is performed per ISO 10555-1, Annex B.	The Arc™ Catheter met the acceptance criteria for Hub/Shaft Peak Tensile Force.
Coating Integrity	Coating Integrity for the Arc™ Catheter was assessed using a staining method pre-and post-	Characterization only.

Arc™ Catheter		
Test	Test Method Summary	Results
	simulation to estimated coating coverage.	
Coating Lubricity/Durability	Coating Lubricity/Durability for the Arc™ Catheter was performed for the average friction force.	The Arc™ Catheter met the acceptance criteria for Coating Lubricity/Durability.
Particulate	Particulate for the Arc™ Catheter was performed in a tortuous model per USP <788>.	Arc™ Catheter met the acceptance criteria for Particulate.
Kink Resistance	Kink Resistance for the Arc™ Catheter is performed with the device wrapped around a rod or known radius at which point the Arc™ Catheter is inspected for kinking.	The Arc™ Catheter met the acceptance criteria for Kink Resistance.
Liquid Leak	Liquid Leak for the Arc™ Catheter is performed per ISO 10555-1, Annex C.	The Arc™ Catheter met the acceptance criteria for Liquid Leak.
Static/Dynamic Burst	Static/Dynamic Burst for the Arc™ Catheter is performed per ISO 10555-1, Annex F.	The Arc™ Catheter met the acceptance criteria for Static/Dynamic Burst.
Corrosion Resistance	Corrosion Resistance for the Arc™ Catheter is performed per ISO 10555-1, Annex A.	The Arc™ Catheter met the acceptance criteria for Corrosion Resistance.
Torque to Failure	The Arc™ Catheter is navigated through a tortuous model where the distal tip is secured, and the proximal end of the catheter is rotated 360°. The total number of 360° rotations prior to failure is recorded.	Characterization only.

The following non-clinical bench testing was performed for the Riptide™ Aspiration Tubing:

Riptide™ Aspiration Tubing		
Test	Test Method Summary	Results
Microbial		
Ethylene Oxide (EO) Residual	EO Residual for the Riptide™ Aspiration Tubing is performed per ISO 10993-7.	The Riptide™ Aspiration Tubing met the acceptance criteria for EO Residual.
Ethylene Chlorohydrin (ECH)	ECH for the Riptide™ Aspiration Tubing is performed per ISO 10993-7.	The Riptide™ Aspiration Tubing met the acceptance criteria for ECH.

Riptide™ Aspiration Tubing		
Test	Test Method Summary	Results
Bioburden Recovery	Bioburden Recovery for the Riptide™ Aspiration Tubing is performed per ANSI/AAMI/ISO 11737-1.	The Riptide™ Aspiration Tubing met the acceptance criteria for Bioburden Recovery.
Bioburden	Bioburden for the Riptide™ Aspiration Tubing is performed per ANSI/AAMI/ISO 11737-1.	The Riptide™ Aspiration Tubing met the acceptance criteria for Bioburden.
Bacterial Endotoxin	Bacterial Endotoxin for the Riptide™ Aspiration Tubing is performed per ANSI/AAMI ST72.	The Riptide™ Aspiration Tubing met the acceptance criteria for Bacterial Endotoxin.
Packaging		
Aseptic Presentation	Aseptic Presentation for the Riptide™ Aspiration Tubing is performed for delamination.	The Riptide™ Aspiration Tubing met the acceptance criteria for Aseptic Presentation.
Seal Width	Seal Width for the Riptide™ Aspiration Tubing is performed per ASTM F2203.	The Riptide™ Aspiration Tubing met the acceptance criteria for Seal Width.
Dye Leak	Dye Leak for the Riptide™ Aspiration Tubing is performed per ASTM F1929.	The Riptide™ Aspiration Tubing met the acceptance criteria for Dye Leak.
Visual Inspection	Visual Inspection for the Riptide™ Aspiration Tubing is performed per ASTM F1886.	The Riptide™ Aspiration Tubing met the acceptance criteria for Visual Inspection.
Bubble Leak	Bubble Leak for the Riptide™ Aspiration Tubing is performed per ASTM F2096.	The Riptide™ Aspiration Tubing met the acceptance criteria for Bubble Leak.
Legibility	Legibility for the Riptide™ Aspiration Tubing is performed for smearing or degradation.	The Riptide™ Aspiration Tubing met the acceptance criteria for Legibility.
Foreign Material	Foreign Material on the Riptide™ Aspiration Tubing is performed via visual inspection.	The Riptide™ Aspiration Tubing met the acceptance criteria for Foreign Material.
Seal Strength	Seal Strength for the Riptide™ Aspiration Tubing is performed per ASTM F88.	The Riptide™ Aspiration Tubing met the acceptance criteria for Seal Strength.
Performance		
Dimensional Inspection	The overall and distal length, proximal and distal inner and outer diameter of the Riptide™ Aspiration Tubing is recorded.	The Riptide™ Aspiration Tubing met the acceptance criteria for Dimensional Inspection.

Riptide™ Aspiration Tubing		
Test	Test Method Summary	Results
Identification of Heat Shrink Bands	The heat shrink bands of the Riptide™ Aspiration Tubing are visually inspected.	The Riptide™ Aspiration Tubing met the acceptance criteria for Identification of the Heat Shrink Bands.
Identification of Flow Switch	The flow switch of the Riptide™ Aspiration Tubing is visually inspected.	The Riptide™ Aspiration Tubing met the acceptance criteria for Identification of the Flow Switch.
Joint Tensile Strength	The Riptide™ Aspiration Tubing is affixed to upper and lower grips of the tensile test fixture and stretched. The maximum value before failure is recorded.	The Riptide™ Aspiration Tubing met the acceptance criteria for Joint Tensile Strength.
Leak	The Riptide™ Aspiration Tubing is pressurized to specified vacuum pressure and any decay in pressure is recorded	The Riptide™ Aspiration Tubing met the acceptance criteria for Leak (Vacuum and Pressure Decay).
Degree of Collapse	Degree of Collapse for the Riptide™ Aspiration Tubing is performed per ISO 10079-3.	The Riptide™ Aspiration Tubing met the acceptance criteria for Degree of Collapse.
Compatibility	The distal end of the Riptide™ Aspiration Tubing is connected to the proximal hub of the Arc™ Catheter. The proximal end of the Riptide™ Aspiration Tubing is connected to the horizontal port of the Riptide™ Collection Canister.	The Riptide™ Aspiration Tubing met the acceptance criteria for Compatibility to the Arc™ Catheter and Riptide™ Collection Canister.

The following non-clinical bench testing was performed for the Riptide™ Aspiration Pump:

Riptide™ Aspiration Pump		
Test	Test Method Summary	Results
Degrees of Tilt	The test axes of the Riptide™ Aspiration Pump are pivoted 45^{o} and does not tip over.	The Riptide™ Aspiration Pump met the acceptance criteria for Degrees of Tilt.
Durability	The Riptide™ Aspiration Pump is functional through 500 hours of expected service life.	The Riptide™ Aspiration Pump met the acceptance criteria for Durability.
Maximum Vacuum	The vacuum control valve of the Riptide™ Aspiration Pump is set to maximum vacuum and	The Riptide™ Aspiration Pump met the acceptance criteria for Maximum Vacuum.

Riptide™ Aspiration Pump		
Test	Test Method Summary	Results
	recorded.	
Flow Capacity	The Riptide™ Aspiration Pump was ran at specified pressure prior to recording the air flow.	The Riptide™ Aspiration Pump met the acceptance criteria for Flow Capacity.
Electrical Safety	Electrical safety for the Riptide™ Aspiration Pump is performed per IEC 60601-1.	The Riptide™ Aspiration Pump met the acceptance criteria for Electrical Safety
Electromagnetic Compatibility	Electromagnetic compatibility for the Riptide™ Aspiration Pump is performed per IEC 60601-1-2.	The Riptide™ Aspiration Pump met the acceptance criteria for Electromagnetic Compatibility.

The following non-clinical bench testing was performed for the Riptide™ Collection Canister with Intermediate Tubing:

Riptide™ Collection Canister with Intermediate Tubing		
Test	Test Method Summary	Results
Packaging		
Packaging Integrity	Packaging Integrity for the Riptide™ Collection Canister with Intermediate Tubing is performed per ISTA 2A and ATSM D4169.	The Riptide™ Collection Canister met the acceptance criteria for Packaging Integrity.
Packaging Labeling	Packaging Labeling for the Riptide™ Collection Canister with Intermediate Tubing is performed to ensure the labeling remains affixed and legible over the labeled shelf life of three (3) months.	The Riptide™ Collection Canister met the acceptance criteria for Packaging Labeling.
Performance		
Volume Capacity	The Riptide™ Collection Canister is visually inspected to ensure graduations up to 1200mL.	The Riptide™ Collection Canister met the acceptance criteria for Volume Capacity.
Volume Marking	The Riptide™ Collection Canister is visually inspected to ensure graduations in 100mL.	The Riptide™ Collection Canister met the acceptance criteria for Volume Marking.
Canister Strength	The Riptide™ Collection Canister is tested for canister strength per ISO 10079-3.	The Riptide™ Collection Canister met the acceptance criteria for Canister Strength.
Overfill Protection	The Riptide™ Collection Canister is tested for overfill	The Riptide™ Collection Canister met the acceptance

Riptide™ Collection Canister with Intermediate Tubing		
Test	Test Method Summary	Results
	protection per ISO 10079-3.	criteria for Overfill Protection.
Dimensional Inspection	The overall length of the Intermediate Tubing is recorded.	The Intermediate Tubing met the acceptance criteria for Dimensional Inspection.
Degree of Collapse	Degree of Collapse for the Intermediate Tubing is performed per ISO 10079-3.	The Intermediate Tubing met the acceptance criteria for Degree of Collapse.
Port Identification	The Riptide™ Collection Canister is visually inspected to ensure the connection ports are correctly labeled.	The Riptide™ Collection Canister met the acceptance criteria for Port Identification.
Compatibility	The Intermediate Tubing is connected to the vacuum inlet port of the Riptide™ Aspiration Pump.	The Intermediate Tubing met the acceptance criteria for Compatibility.

The following non-clinical bench testing was performed for the Riptide™ Aspiration System:

Riptide™ Aspiration System		
Test	Test Method Summary	Results
Simulated Clot Retrieval	The Arc™ Catheter is navigated through a tortuous model to the intended treatment location for simulated clot retrieval.	The Riptide™ Aspiration System met the acceptance criteria for Simulated Clot Retrieval.
Vacuum Pressure	The vacuum pressure experienced at the distal tip of the Arc™ Catheter is recorded.	The Riptide™ Aspiration System met the acceptance criteria for Vacuum Pressure.
Flow Rate	The flow rate through the Arc™ Catheter is recorded under full-flow conditions.	The Riptide™ Aspiration System met the acceptance criteria for Flow Rate.
Lumen Collapse	The Arc™ Catheter is navigated through a tortuous model and subjected to maximum vacuum pressure generated by the Riptide™ Aspiration Pump at which point the catheter is inspected for any collapse or damage.	The Arc™ Catheter is resistant to Lumen Collapse.
Usability	The Penumbra System® and Penumbra Pump MAX™ and the Riptide™ Aspiration System were evaluated for navigability, flexibility, the	The Riptide™ Aspiration System met the acceptance criteria for Usability.

Riptide™ Aspiration System		
Test	Test Method Summary	Results
	ability to engage and apply aspiration, and for the ability to safely retrieve clot by end users.	

The non-clinical bench testing, as described above, indicates that the Riptide™ Aspiration System is substantially equivalent to the Penumbra System® and Penumbra Pump MAX™.

Performance Data – Animal:
Non-clinical animal testing was performed to evaluate the safety, efficacy, and usability of the Riptide™ Aspiration System in comparison to the Penumbra System® and Penumbra Pump MAX™ at acute and chronic time points in a porcine model, both in the presence and absence of simulated clot. Non-clinical animal testing was performed in accordance with 21 CFR Part 58 for Good Laboratory Practice (GLP) for Non-Clinical Laboratory Studies.

The non-clinical animal testing, as described above, indicates that the Riptide™ Aspiration System is substantially equivalent to the Penumbra System® and Penumbra Pump MAX™.

Performance Data – Clinical:
Not Applicable. A determination of substantial equivalence is based upon non-clinical bench and animal testing.

Conclusion:
The design modifications incorporated into the Riptide™ Aspiration System do not alter the fundamental scientific technology or intended use.

Non-clinical bench and animal testing supports a determination that the subject Riptide™ Aspiration System is substantially equivalent to the predicate Penumbra System® and Penumbra Pump MAX™.