April 19, 2018

InNeuroCo, Inc.
Marianne Grunwaldt
Director, Quality Assurance and Regulatory Affairs
4635 NW 103rd Avenue
Sunrise, Florida 33351

Re: K172167
Trade/Device Name: Zenith Flex System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NRY, DTL, DYB
Dated: April 13, 2018
Received: April 16, 2018

Dear Marianne Grunwaldt:

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 FDA

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)*
K172167

Device Name
Zenith Flex System

Indications for Use *(Describe)*
The Zenith Flex System, including the Zenith Flex Catheter, Aspiration Tubing Set, and VC-701 Cliq Aspirator Pump, is indicated 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 failed 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 **- K172167**

Submitter's Name and Address

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Date Prepared

April 11, 2018

Device Trade or Proprietary Name

Zenith Flex System

Device Common or Classification Name:

Catheter, Percutaneous, 21CFR870.1250, Class II
Hemostasis Valve, 21CFR870.4290, Class II
Catheter Introducer, 21 CFR 870.1340, Class II

Product Code:

NRY (Catheter)
DTL (Hemostasis Valve)
DYB (Catheter Introducer)

Identification of the Legally Marketed Devices to which Equivalence is Being Claimed

Name of Predicate Device	Name of Manufacturer	510(k) Number
Penumbra System ACE 68 Reperfusion Catheter	Penumbra, Inc	K161064

Device Description

The Zenith Flex System consists of the Zenith Flex Catheter, the VC-701 Cliq Aspirator Pump and the Aspiration Tubing Set. The InNeuroCo Zenith Flex Catheter is a variable stiffness catheter that has a catheter shaft reinforced with Stainless-Steel and Nitinol to provide support. The Stainless-Steel is wound as a double coil in the proximal section and the Nitinol is a single coil in the distal section. It has a radiopaque Platinum/Iridium marker band on the distal end. The distal 25 cm of the Zenith Flex Catheter has a hydrophilic coating. The Zenith Flex Catheter is available with an internal diameter of 0.0715 inch. The outer diameter is of 0.0850 inch in the proximal section, and tapers to a nominal of 0.082 inch in the distal section. The Zenith Flex Catheter is available in three working lengths: 115 cm, 125 cm, and 132 cm. Accessories included with the device are a Tuohy-Borst Hemostasis Valve and two peel-away Introducers and a Scout introducer. The Scout may be used to introduce the Zenith Flex Catheter into distal vasculature, thereby helping the device reach the target anatomy. The Zenith Flex Catheter is supplied sterile, non-pyrogenic, and intended for single use only. The off-the-shelf aspiration pump is provided non-sterile.

Indications for Use

The Zenith Flex System, including the Zenith Flex Catheter, Aspiration Tubing Set, and VC-701 Cliq Aspirator Pump, is indicated 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 failed IV t-PA therapy are candidates for treatment.

Comparison to Predicate Device

	Predicate Device Penumbra Ace 68	InNeuroCo, Inc. Zenith Flex System
510(k) Number	K161064	K172167
Classification	Class II	Class II
Product Code	NRY	NRY
Review Panel	Neurology	Neurology
Indications For Use	The Penumbra 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.	The Zenith Flex System, including the Zenith Flex Catheter, Aspiration Tubing Set, and VC-701 Cliq Aspirator Pump, is indicated 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 failed IV t-PA therapy are candidates for treatment.
Components Supplied	Penumbra Reperfusion Catheter, Aspiration Pump, Pump/Canister Tubing, Aspiration Tubing, Separator	Zenith Flex Catheter, Peel Away Introducer, Hemostasis Valve, Scout Introducer, VC-701 Cliq Aspirator Pump, Aspiration Tubing Set

	Predicate Device Penumbra Ace 68	InNeuroCo, Inc. Zenith Flex System (Zenith Flex Catheter)
Catheter Shaft Material	Pebax, Nylon, Urethane	Polyether Block Amide (PEBAX), Polycarbonate/Urethane, Nylon
Inner Liner	PTFE	Same
Hub Material	Polycarbonate	Same
Strain Relief	Polyolefin	Same
Catheter Shaft Reinforcement	Stainless Steel/Nitinol	Same
Reinforcement pattern	Coil	Braid
Lubricious Coating	Hydrophilic Coating	Same
Radiopaque Marker Band	Platinum/ Iridium	Same
Packaging	Tyvek/Nylon Pouch, polyethylene support tube, packaging card, SBS carton	Tyvek/Nylon Pouch, polyethylene support tube, packaging card, SBS carton
Sterilization	Ethylene Oxide	Ethylene Oxide
Pyrogenicity	Nonpyrogenic	Nonpyrogenic
Working Lengths	115, 120, 125, 127, 132 cm	115, 125, 132 cm
Inside Diameter (ID)	0.068 inch min.	0.071 inch
Proximal Outer Diameter	0.084 inch max	0.085 inch
Distal Outer Diameter	0.084 inch max	0.082 inch nominal
Shelf Life	3 years	3 years
Introducer	Included as part of the Separator with a torque device	Peelaway to aid in catheter tip introduction into hemostasis valve Scout to help with the navigation
Hemostasis Valve	Polycarbonate, Silicone O-Ring, Side Port	Same
Luer Tapered Hub	Yes	Yes
Compatible Guidewire	0.038 inch	0.038 inch
Scout Introducer	No	Yes
Aspiration Method	Pump	Same
Aspiration Pressure	20-29 in Hg	26.6 in Hg

	Predicate Device Penumbra Aspiration Tubing	InNeuroCo, Inc. Zenith Flex System (Aspiration Tubing Set)
Components Supplied	Tubing, Flow Control Switch, Luer Fittings, Vacuum connector	SAME
Control Switch identifies ON/OFF	Yes	SAME
Materials	Biocompatible, commonly utilized for interventional devices	SAME
Tubing OD	0.188 inch	0.142 inch
Tubing ID	0.071 inch to 0.110 inch	0.071 inch
Overall Length	112.0 inch	84.0 inch
Display Carton	SBS Paperboard	SAME
Packaging Configuration	Individual	SAME
Sterilization	EO	SAME
Shelf Life	36 Months	SAME

	Predicate Device Penumbra Ace 68	InNeuroCo, Inc. Zenith Flex System (VC-701 Cliq Aspirator Pump)
IEC 60601-1 Compliance	Yes	SAME
IEC 60601-2 Compliance	Yes	SAME
Voltage	110 VAC to 115 VAC	110 VAC to 120 VAC
Frequency	50/60 Hz	60 Hz
Sterilization	Non-Sterile	SAME
Shelf Life	N/A	SAME
Ability to function as a system	Yes	SAME
Specified Pressure Ranges	29 in Hg max	27 in Hg max
Measured Pressure Ranges	26 in Hg max	27 in Hg max
Maximum duration of time the pump can operate while producing pressures that are clinically significant	After 4 hours of continuous use, measured pressures ranges are retained	SAME
Insulated handle	Yes	SAME
Pressure gage range	0-760 mm Hg	SAME

Summary of Non-Clinical Data

Biocompatibility tests conducted with the Zenith Flex Catheter and its accessories were selected in accordance with ISO 10993-1 guidelines (Biological Evaluation of Medical Devices) for limited duration (≤ 24 hours), external communicating devices, contacting circulating blood. Studies were conducted pursuant to 21CFR58, Good Laboratory Practices. Biocompatibility testing found the Zenith Flex Catheter to be biocompatible and non-pyrogenic.

Biocompatibility tests conducted with the Aspiration Tubing Set were selected in accordance with ISO 10993-1 guidelines (Biological Evaluation of Medical Devices) for a surface device in contact with intact skin for limited (≤ 24 hours) duration. Studies were conducted pursuant to 21CFR58, Good Laboratory Practices. Biocompatibility testing found the Aspiration Tubing Set to be biocompatible.

The conclusions drawn from the physical, mechanical, and performance testing of the subject Zenith Flex System demonstrates that the product is Substantially Equivalent to the legally marketed predicate device.

Animal Testing

Clot was used to create occlusions within several arteries of swine. One side of each swine was treated with the Zenith Flex Catheter and the contralateral side was treated with predicate device. The study included two follow up evaluations: 3 days and 30 days. There were 3 endpoints of the study: angiographic assessment of revascularization to establish effectiveness, angiographic assessment and histopathological assessment to demonstrate safety. As testing included the predicate device, results were compared to demonstrate substantial equivalence.

Zenith Flex Performance Testing

Test	Test Method Summary	Acceptance Criteria	Conclusions
Zenith Flex Catheter & its accessories Biocompatibility- Material Mediated Pyrogen	Testing completed per ISO 10993-11	The test article extracts must not cause a febrile reaction greater than 0.5°C in any individual subject.	Test results for the Zenith Catheter (K171672) were leveraged for the Zenith Flex Catheter as the materials and manufacturing processes are equivalent. Test articles met the acceptance criteria.
Zenith Flex Catheter & its accessories Biocompatibility- Cytotoxicity MEM Elution	Testing completed per ISO 10993-5	The cultures treated with the test article must not have a reactivity grade greater than 2.	Test results for the Zenith Catheter (K171672) were leveraged for the Zenith Flex Catheter as the materials and manufacturing processes are equivalent. Test articles met the acceptance criteria.
Zenith Flex Catheter & its accessories Biocompatibility- Hemolysis ASTM Method, extract human blood	Testing completed per ISO 10993-4	The hemolytic index above the negative control article must be less than 5%.	Test results for the Zenith Catheter (K171672) were leveraged for the Zenith Flex Catheter as the materials and manufacturing processes are equivalent. Test articles met the acceptance criteria.
Zenith Flex Catheter & its accessories Biocompatibility- Hemolysis, ASTM	Testing completed per ISO 10993-4	The hemolytic index above the negative control article must be less than 5%.	Test results for the Zenith Catheter (K171672) were leveraged for the Zenith Flex Catheter as the materials and manufacturing processes are equivalent. Test articles met the acceptance criteria.

Test	Test Method Summary	Acceptance Criteria	Conclusions
Zenith Flex Catheter & its accessories Biocompatibility-Unactivated Partial Thromboplastin Time	Testing completed per ISO 10993-4	There must be no statistical decrease between the UPTT of plasma exposed to the test article and to the negative or untreated control.	Test results for the Zenith Catheter (K171672) were leveraged for the Zenith Flex Catheter as the materials and manufacturing processes are equivalent. Test articles met the acceptance criteria.
Zenith Flex Catheter & its accessories Biocompatibility-Complement Activation	Testing completed per ISO 10993-4	There must be no statistical increase between either the C3a or SC5b-9 concentrations in plasma exposed to the test article as compared to the negative and untreated controls.	Test results for the Zenith Catheter (K171672) were leveraged for the Zenith Flex Catheter as the materials and manufacturing processes are equivalent. Test articles met the acceptance criteria.
Zenith Flex Catheter & its accessories Biocompatibility-Dog Thromboresistance	Testing completed per ISO 10993-4	The test articles must receive a thrombus formation score less than or equal to that of the control.	Test results for the Zenith Catheter (K171672) were leveraged for the Zenith Flex Catheter as the materials and manufacturing processes are equivalent. Test articles met the acceptance criteria.
Zenith Flex Catheter & its accessories Biocompatibility-Maximization Sensitization	Testing completed per ISO 10993-10	The test article must elicit a positive response in less than 10% of the test animals.	Test results for the Zenith Catheter (K171672) were leveraged for the Zenith Flex Catheteras the materials and manufacturing processes are equivalent. Test articles met the acceptance criteria.

Test	Test Method Summary	Acceptance Criteria	Conclusions
Zenith Flex Catheter & its accessories Biocompatibility-Intracutaneous Toxicity/Reactivity	Testing completed per ISO 10993-10	The test article extracts must not induce a significantly greater biological reaction than the control.	Test results for the Zenith Catheter (K171672) were leveraged for the Zenith Flex Catheter as the materials and manufacturing processes are equivalent. Test articles met the acceptance criteria.
Zenith Flex Catheter & its accessories Biocompatibility-Acute Systemic Toxicity Test	Testing completed per ISO 10993-11	The test article extracts must not induce a significantly greater biological reaction than the control.	Test results for the Zenith Catheter (K171672) were leveraged for the Zenith Flex Catheter as the materials and manufacturing processes are equivalent. Test articles met the acceptance criteria.
Chemical Compatibility (Zenith Flex Catheter)	Catheter exposed to chemicals readily available in a clinical setting.	Product shall withstand exposure to chemicals without degradation.	Zenith Flex Catheter test samples met the acceptance criteria for Chemical Compatibility to demonstrate that the Zenith Flex Catheter is substantially equivalent to the predicate device.
Radiographic Detectability (Zenith Flex Catheter)	Testing completed per ISO 10555-1	Product shall be visible under fluoro imaging.	Zenith Flex Catheter test samples met the acceptance criteria for Radiographic Detectability to demonstrate that the Zenith Flex Catheter is substantially equivalent to the predicate device.
Visual Inspection (Zenith Flex Catheter)	Testing completed per ISO 10555-1	Test samples should meet visual inspection specifications.	Zenith Flex Catheter test samples met the acceptance criteria for Visual Inspection to demonstrate that the Zenith Flex is substantially equivalent to the predicate device.

Test	Test Method Summary	Acceptance Criteria	Conclusions
Working Length (Zenith Flex Catheter)	Testing completed per ISO 10555-1	Test samples should be within existing working length specification.	Zenith Flex Catheter test samples met the acceptance criteria for Working Length to demonstrate that the Zenith Flex Catheter is substantially equivalent to the predicate device.
Hub compatibility (Zenith Flex Catheter)	Testing completed per ISO 594-1 and ISO 594-2	Hub shall meet existing Luer specifications.	Test results for the Zenith Catheter (K171672) were leveraged for the Zenith Flex Catheter as the materials and manufacturing processes are equivalent. Test articles met the acceptance criteria.
Outside diameter (Zenith Flex Catheter)	Testing completed per ISO 10555-1	Test samples should be within existing outside diameter specification.	Zenith Flex Catheter test samples met the acceptance criteria for Outside diameter to demonstrate that the Zenith Flex Catheter is substantially equivalent to the predicate device.
Leak – Air (Zenith Flex Catheter)	Testing completed per ISO 10555-1	Test samples should be within existing Air – Leak specifications.	Zenith Flex Catheter test samples met the acceptance criteria for Leak – Air to demonstrate that the Zenith Flex Catheter is substantially equivalent to the predicate device.
Leak – Liquid (Zenith Flex Catheter)	Testing completed per ISO 10555-1	Test samples should be within existing Leak – Liquid specifications.	Zenith Flex Catheter test samples met the acceptance criteria for Leak – Liquid to demonstrate that the Zenith Flex Catheter is substantially equivalent to the predicate device.

Test	Test Method Summary	Acceptance Criteria	Conclusions
Particulates (Zenith Flex Catheter)	Samples conditioned in benchtop anatomical model. Testing completed per USP 788	Test samples should be within existing Particulate specifications.	Zenith Flex Catheter test samples met the acceptance criteria for Particulates to demonstrate that the Zenith Flex Catheter is substantially equivalent to the predicate device.
Simulated Use – Bench (Zenith Flex Catheter)	Zenith Flex underwent simulated use testing by a physician in a benchtop model	Test samples must meet predetermined user needs	Zenith Flex Catheter test samples met the acceptance criteria for Simulated Use - Bench to demonstrate that the Zenith Flex Catheter is substantially equivalent to the predicate device.
Catheter Burst (Zenith Flex Catheter)	Testing completed per ISO 10555-1	Test sample burst pressures must meet or exceed existing minimum burst pressure specification.	Zenith Flex Catheter test samples met the acceptance criteria for Catheter Burst to demonstrate that the Zenith Flex Catheter is substantially equivalent to the predicate device.
Tensile (Zenith Flex Catheter)	Testing completed per ISO 10555-1	Test sample ultimate tensile strength must meet or exceed existing tensile strength specifications.	Zenith Flex Catheter test samples met the acceptance criteria for Tensile to demonstrate that the Zenith Flex Catheter is substantially equivalent to the predicate device.

Test	Test Method Summary	Acceptance Criteria	Conclusions
Corrosion (Zenith Flex Catheter)	Testing completed per ISO 10555-1	Test samples shall exhibit no evidence of corrosion.	Test results for the Intermediate Catheter (K152202) were leveraged for the Zenith Flex Catheter as the materials and manufacturing processes are equivalent. Test articles met the acceptance criteria.
Packaging – Dye Leak (Zenith Flex Catheter)	Testing completed per ASTM F1929-12	Test sample shall not exhibit any visual leaks or channels	Test results for the Zenith (K171672) were leveraged for the Zenith Flex Catheter as the materials and manufacturing processes are equivalent. Test articles met the acceptance criteria.
Packaging – Peel (Zenith Flex Catheter)	Testing completed per ASTM F88-09	Test sample tensile strength must meet or exceed existing tensile strength specifications.	Test results for the Zenith (K171672) were leveraged for the Zenith Flex Catheter as the materials and manufacturing processes are equivalent. Test articles met the acceptance criteria.
Kink Resistance (Zenith Flex Catheter)	Samples are subjected to different diameters until kink is observed.	Test sample kink resistance must meet or exceed existing Kink Resistance specifications.	Zenith Flex Catheter test samples met the acceptance criteria for Kink Resistance to demonstrate that the Zenith Flex Catheter is substantially equivalent to the predicate device.
Torque (Zenith Flex Catheter)	Conditioned samples are torqued to failure	Test sample torque results must meet or exceed existing torque specifications.	Zenith Flex Catheter test samples met the acceptance criteria for Torque to demonstrate that the Zenith Flex Catheter is substantially equivalent to the predicate device.

Test	Test Method Summary	Acceptance Criteria	Conclusions
PTFE Liner inspection (Zenith Flex Catheter)	Zenith Flex was challenged to demonstrate liner adherence.	Test sample liner adhesion must meet or exceed existing PTFE Liner inspection specifications.	Zenith Flex Catheter test samples met the acceptance criteria for PTFE Liner inspection to demonstrate that the Zenith Flex Catheter is substantially equivalent to the predicate device.
Hydrophilic Coating Integrity (Zenith Flex Catheter)	Conditioned samples were repeatedly exposed to friction and introduced into an anatomical model to demonstrate that the hydrophilic coating is not affected.	Test sample results must meet or exceed existing Hydrophilic Coating Integrity specifications.	Zenith Flex Catheter test samples met the acceptance criteria for Hydrophilic Coating Integrity to demonstrate that the Zenith Flex Catheter is substantially equivalent to the predicate device.
Aspiration (Zenith Flex System)	Using a simulated model, the samples retrieved thrombi with an aspiration pump	Successfully removed the thrombi	Zenith Flex System test samples met the acceptance criteria for Aspiration to demonstrate that the Zenith Flex System is substantially equivalent to the predicate device
Labeling Legibility	Label is legible after printing.	Test samples shall demonstrate text legibility.	Test results for the Zenith Catheter (K171672) were leveraged for the Zenith Flex Catheter as the materials and manufacturing processes are equivalent. Test articles met the acceptance criteria.
Barcode	Barcode is readable with a standard barcode reader.	Test samples shall demonstrate readily readable barcodes	Test results for the Zenith Catheter (K171672) were leveraged for the Zenith Flex as the materials and manufacturing processes are equivalent. Test articles met the acceptance criteria.

Test	Test Method Summary	Acceptance Criteria	Conclusions
Sterilization (Zenith Flex Catheter & Aspiration Tubing Set)	ISO 11135 and AAMI TIR 28	Sterilization load shall pose an equal or lesser challenge to sterilize than existing sterile product loads.	Sterilization loads met the acceptance criteria for sterilization to demonstrate that the Zenith Flex and the Aspiration Tubing Set is substantially equivalent to the predicate device.
Shelf Life (Zenith Flex Catheter & Aspiration Tubing Set)	ASTM F1980	Aged test samples must meet or exceed existing specifications	Zenith Flex Catheter & Aspiration Tubing Set test samples met the acceptance criteria for shelf life to demonstrate that the Zenith Flex Catheter & Aspiration Tubing Set are substantially equivalent to the predicate device.
Toque Strength (Zenith Flex Catheter)	Samples were placed in anatomical model and torqued until failure	Test sample results must meet or exceed existing torque specifications.	Zenith Flex Catheter test samples met the acceptance criteria for torque to demonstrate that the Zenith Flex Catheter is substantially equivalent to the predicate device.
Kink Resistance (Zenith Flex Catheter)	Reduction in flow was evaluated while samples were exposed to appropriate tortuosity	Test sample results must meet or exceed existing kink resistance specifications.	Zenith Flex Catheter test samples met the acceptance criteria for kink resistance to demonstrate that the Zenith Flex Catheter is substantially equivalent to the predicate device.
Lumen Patency (Zenith Flex Catheter)	Samples were placed in benchtop anatomical model and evaluated for lumen collapse during aspiration	Test sample results must meet or exceed existing lumen patency specifications.	Zenith Flex Catheter test samples met the acceptance criteria for lumen patency to demonstrate that the Zenith Flex Catheter is substantially equivalent to the predicate device.

Test	Test Method Summary	Acceptance Criteria	Conclusions
Tip Flexibility (Zenith Flex Catheter)	Samples were deflected, and associated forces were measured	Zenith Flex tip flexibility results were compared to predicate device results.	Zenith Flex Catheter test samples performed comparatively against the predicate device demonstrating that the Zenith Flex Catheter is substantially equivalent to the predicate device.
Friction Force (Zenith Flex Catheter)	Samples were tracked through benchtop anatomical model and frictional forces were measured	Zenith Flex friction force results were compared to predicate device results.	Zenith Flex Catheter test samples performed comparatively against the predicate device demonstrating that the Zenith Flex Catheter is substantially equivalent to the predicate device.
Simulated Use Testing – Usability (Zenith Flex System)	Zenith Flex underwent simulated use testing by a physician in a benchtop model	Test samples must meet predetermined user needs	Zenith Flex System test samples met the acceptance criteria for Simulated Use - Usability to demonstrate that the Zenith Flex System is substantially equivalent to the predicate device.
Visual Inspection (Aspiration Tubing Set)	Finished Devices were inspected for damage visually	Test samples should meet visual inspection specifications.	Aspiration Tubing Set test samples met the acceptance criteria for Visual Inspection to demonstrate that the Aspiration Tubing Set is substantially equivalent to the predicate device.
Tensile (Aspiration Tubing Set)	Finished devices were elongated until failure	Test sample ultimate tensile strength must meet or exceed existing tensile strength specifications.	Aspiration Tubing Set test samples met the acceptance criteria for Tensile to demonstrate that the Aspiration Tubing Set is substantially equivalent to the predicate device.

Test	Test Method Summary	Acceptance Criteria	Conclusions
Leak – Liquid (Aspiration Tubing Set)	Tubing pressurized with fluid and inspected for leak	Test samples should be within existing Leak – Liquid specifications.	Aspiration Tubing Set test samples met the acceptance criteria for Leak – Liquid to demonstrate that the Aspiration Tubing Set is substantially equivalent to the predicate device.
Leak – Air, Tubing and Control Switch (Aspiration Tubing Set)	Tubing samples evaluated for air leak during aspiration	Test samples should be within existing Air – Leak specifications.	Aspiration Tubing Set test samples met the acceptance criteria for Leak – Air to demonstrate that the Aspiration Tubing Set is substantially equivalent to the predicate device.
Luer Compatibility (Aspiration Tubing Set)	Testing completed per ISO 80369-7	Hub shall meet existing Luer specifications.	Aspiration Tubing Set test samples met the acceptance criteria for Luer compatibility to demonstrate that the Aspiration Tubing Set is substantially equivalent to the predicate device.
Suction Connector Separation Force (Aspiration Tubing Set)	Force to separate suction connector from cannister was evaluated using force gauge	Test sample results must meet or exceed existing force specifications.	Aspiration Tubing Set test samples met the acceptance criteria for separation force to demonstrate that the Aspiration Tubing Set is substantially equivalent to the predicate device.
Vacuum Drop / Suction Connector Secure Attachment (Aspiration Tubing Set)	Vacuum pressure measured at source and tip to evaluate pressure difference	Test sample results must meet or exceed existing pressure specifications.	Aspiration Tubing Set test samples met the acceptance criteria for vacuum drop to demonstrate that the Aspiration Tubing Set is substantially equivalent to the predicate device.

Test	Test Method Summary	Acceptance Criteria	Conclusions
Lumen Patency (Aspiration Tubing Set)	Samples were evaluated for lumen collapse during aspiration	Test sample results must meet or exceed existing lumen patency specifications.	Aspiration Tubing Set test samples met the acceptance criteria for lumen patency to demonstrate that the Aspiration Tubing Set is substantially equivalent to the predicate device.
Dimensions (Aspiration Tubing Set)	Critical dimensions were measured.	Test samples should be within existing dimensional specifications.	Aspiration Tubing Set test samples met the acceptance criteria for dimensions to demonstrate that the Aspiration Tubing Set is substantially equivalent to the predicate device.
Packaging – Dye Leak (Zenith Flex Catheter and Aspiration Tubing Set)	Testing completed per ASTM F1929-12	Test sample shall not exhibit any visual leaks or channels	Zenith Flex Catheter and Aspiration Tubing Set test samples met the acceptance criteria for Packaging – Dye Leak to demonstrate that the Zenith Flex Catheter and the Aspiration Tubing Set are substantially equivalent to the predicate device
Packaging – Peel (Zenith Flex Catheter and Aspiration Tubing Set)	Testing completed per ASTM F88-09	Test sample tensile strength must meet or exceed existing tensile strength specifications.	Zenith Flex Catheter and Aspiration Tubing Set test samples met the acceptance criteria for Packaging - Peel to demonstrate that the Zenith Flex and the Aspiration Tubing Set are substantially equivalent to the predicate device.

Test	Test Method	Acceptance Criteria	Conclusions
Aspiration Tubing Set Biocompatibility-Cytotoxicity MEM Elution	Testing completed per ISO 10993-5	The cultures treated with the test article must not have a reactivity grade greater than 2.	Aspiration Tubing Set Test articles met the acceptance criteria for Cytotoxicity to demonstrate that the Aspiration Tubing Set is substantially equivalent to the predicate device.
Aspiration Tubing Set Biocompatibility-Maximization Sensitization	Testing completed per ISO 10993-10	The test article must elicit a positive response in less than 10% of the test animals.	Aspiration Tubing Set Test articles met the acceptance criteria for Maximization Sensitization to demonstrate that the Aspiration Tubing Set is substantially equivalent to the predicate device.
Aspiration Tubing Set Biocompatibility-Intracutaneous Toxicity/Reactivity	Testing completed per ISO 10993-10	The test article extracts must not induce a significantly greater biological reaction than the control.	Aspiration Tubing Set Test articles met the acceptance criteria for Intracutaneous Toxicity/Reactivity to demonstrate that the Aspiration Tubing Set is substantially equivalent to the predicate device.

Performance Data – Clinical

No clinical study was conducted as bench and animal testing was determined sufficient for verification and validation purposes. A review was conducted considering published clinical study articles that featured the Predicate Device and other devices with similar dimensions used for direct aspiration. The literature review was used to support the proposed indications for use under the NRY product code by leveraging clinical outcomes from devices that are considered technologically similar.