October 25, 2018

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

Re: K181354
Trade/Device Name: Zenith Flex System (074 Zenith Flex Catheter)
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NRY, DTL, DYB
Dated: September 21, 2018
Received: September 25, 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Xiaolin Zheng -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

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)*

K181354

Device Name

Zenith Flex System (074 Zenith Flex Catheter)

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

K181354

Submitter's Name and Address

InNeuroCo, Inc.
4635 NW 103rd Avenue
Sunrise, Florida 33351
Telephone: 1-954-742-5988
Facsimile: 1-954-742-5989

Contact Information

Marianne Grunwaldt
Director, Quality Assurance &
Regulatory Affairs
InNeuroCo, Inc
4635 NW 103rd Avenue
Sunrise, Florida 33351
Telephone: 1-305-495-3883
Facsimile: 1-954-742-5989
E-Mail: Marianne@InNeuroCo.com

Secondary Contact

Ming Cheng Chew
Regulatory Consultant, Libra Medical, Inc.
8401 73rd Ave N, Suite 63
Brooklyn Park, MN 55428
Telephone: 763-232-3701
E-Mail: mcchew@libramed.com

Date Prepared

October 22, 2018

Device Trade or Proprietary Name

Zenith Flex System (074 Zenith Flex Catheter)

Device Common or Classification Name:

Percutaneous Catheter, 21 CFR 870.1250, Class II
Hemostasis Valve, 21 CFR 870.4290, Class II
Catheter Introducer, 21 CFR 870.1340, Class II

Product Code:

NRY (Catheter, Thrombus Retriever)
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
Zenith Flex Catheter	InNeuroCo, Inc	K172167
Name of Reference Device	**Name of Manufacturer**	**510(k) Number**
ACE 68	Penumbra	K161064

Device Description

The InNeuroCo 074 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 074 Zenith Flex Catheter has a hydrophilic coating. The 074 Zenith Flex Catheter is available with an internal diameter of 0.074 inches. The outer diameter is of 0.089 inches along its proximal shaft, and 0.083 inches along its distal shaft. The 074 Zenith Flex Catheter is available in three working lengths: 115 cm, 125 cm, and 132 cm. The 074 Zenith Flex Catheter has a PTFE lined lumen. Accessories included with the device are a Tuohy-Borst Hemostasis Valve, two peel-away Introducers, and a Scout introducer. The Scout may be used to introduce the 074 Zenith Flex Catheter into distal vasculature, thereby helping the device reach the target anatomy.

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 InNeuroCo, Inc. 071 Zenith Flex	Reference Device Penumbra Ace 68	Subject Device InNeuroCo, Inc. 074 Zenith Flex
510(k) Number	K172167	K161064	K181354
Classification	Class II	Class II	Same
Product Code	NRY	NRY	Same
Review Panel	Neurology	Neurology	Same
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.	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.	Same as 071 Zenith Flex

	Predicate Device InNeuroCo, Inc. 071 Zenith Flex	Reference Device Penumbra Ace 68	Subject Device InNeuroCo, Inc. 074 Zenith Flex
Components Supplied	Zenith Flex Catheter, Peel Away Introducer, Hemostasis Valve, Scout Introducer	Penumbra Reperfusion Catheter, Aspiration Pump, Pump/Canister	Same as 071 Zenith Flex
Catheter Shaft Material	Polyether Block Amide (PEBAX), Polycarbonate/Urethane, Nylon	Pebax, Nylon, Urethane	Same as 071 Zenith Flex
Inner Liner	PTFE	PTFE	Same
Hub Material	Polycarbonate	Grilamid	Same as 071 Zenith Flex
Strain Relief	Polyolefin	Polyolefin, PET Yellow, Grilamid	Same as 071 Zenith Flex
Catheter Shaft Reinforcement	Stainless Steel/Nitinol	Stainless Steel/Nitinol	Same
Reinforcement pattern	Coil	Coil	Same
Lubricious Coating	Hydrophilic Coating	Hydrophilic Coating	Same
Radiopaque Marker Band	Platinum/ Iridium	Platinum/ Iridium	Same
Catheter Packaging	Tyvek/Nylon Pouch, polyethylene support tube, packaging card, SBS carton	Tyvek/Nylon Pouch, polyethylene support tube, packaging card, SBS carton	Same
Sterilization	Ethylene Oxide	Ethylene Oxide	Same
Pyrogenicity	Nonpyrogenic	Nonpyrogenic	Same
Working Lengths	115, 125, 132 cm	115, 120, 125, 127, 132 cm	Same as 071 Zenith Flex
Inside Diameter (ID)	0.071 in	0.068 in min.	0.074 in

	Predicate Device InNeuroCo, Inc. 071 Zenith Flex	Reference Device Penumbra Ace 68	Subject Device InNeuroCo, Inc. 074 Zenith Flex
Proximal Outer Diameter	0.085 in max	0.084 in max	0.089 in max
Distal Outer Diameter	0.082 in nominal	0.084 in max	0.083 in nominal
Shelf Life	3 years	3 years	Same
Introducer	Peel away to aid in catheter tip introduction into hemostasis valve Scout to help with the navigation	Included as part of the Separator with a torque device	Same as 071 Zenith Flex
Hemostasis Valve	Polycarbonate, Silicone O-Ring, Side Port	Polycarbonate, Silicone O-Ring, Side Port	Same
Luer Tapered Hub	Yes	Yes	Same
Compatible Guidewire	0.038 inches	0.038 inches	Same
Scout Introducer	Yes	No	Same as 071 Zenith Flex
Aspiration Method	Pump	Pump	Same
Aspiration Pressure	22-28 in Hg	20-29 in Hg	Same as 071 Zenith Flex

Summary of Non-Clinical Data

The subject device has the same materials, packaging, manufacturing process, and sterilization process as the predicate device. Therefore, testing was only conducted for specifications that were affected by the catheter size change.

Animal Testing

Clot was used to create occlusions within several arteries of swine. One side of each swine was treated with the subject Zenith Flex system and the contralateral side was treated with the reference 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 reference device, results were compared to demonstrate substantial equivalence.

Zenith Flex Performance Testing

To demonstrate substantial equivalence between the subject 074 Zenith Flex Catheter and the predicate 071 Zenith Flex Catheter and the reference Penumbra ACE 68 Catheter, performance testing was conducted. The testing covered verification and validation testing, including biocompatibility, bench testing, sterilization and shelf life. Additionally, some tests were leveraged from previous testing conducted by InNeuroCo. The tests were performed using standard test methods and pre-determined acceptance criteria and all samples passed. Therefore, this test data supports the argument that the 074 Zenith Flex Catheter has similar performance characteristics as the predicate device and the reference device. All of the testing conducted to demonstrate substantial equivalence are presented in the following table.

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 Flex Catheter (K172167) were leveraged for the subject 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 Flex Catheter (K172167) were leveraged for the subject 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 Flex Catheter (K172167) were leveraged for the subject Zenith Flex Catheter as the materials and manufacturing processes are equivalent. Test articles met the acceptance

Test	Test Method Summary	Acceptance Criteria	Conclusions
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 Flex Catheter (K172167) were leveraged for the subject Zenith Flex Catheter as the materials and manufacturing processes are equivalent. Test articles met the acceptance criteria.
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 Flex Catheter (K172167) were leveraged for the subject 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 Flex Catheter (K172167) were leveraged for the subject 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 Flex Catheter (K172167) were leveraged for the subject 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 Flex Catheter (K172167) were leveraged for the subject 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-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 Flex Catheter (K172167) were leveraged for the subject 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 Flex Catheter (K172167) were leveraged for the subject 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.	Test results for the Zenith Flex Catheter (K172167) were leveraged for the subject Zenith Flex Catheter as the materials and manufacturing processes are equivalent. Test articles met the acceptance criteria.
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 subject Zenith Flex Catheter as the materials and manufacturing processes are equivalent. Test articles met the acceptance criteria.

Test	Test Method Summary	Acceptance Criteria	Conclusions
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 Catheteris 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.
Particulates (Zenith Flex Catheter)	Samples conditioned in benchtop anatomical model. Testing completed per USP 788	Test samples should be within existing Particulate specifications.	Test results for the Zenith Flex Catheter (K172167) were leveraged for the subject Zenith Flex Catheter as the materials and manufacturing processes are equivalent. Test articles met the acceptance
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.

Test	Test Method Summary	Acceptance Criteria	Conclusions
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.
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 subject Zenith Flex Catheter as the materials and manufacturing processes are equivalent. Test articles met the acceptance criteria.
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.	Test results for the Zenith Flex Catheter (K172167) were leveraged for the subject Zenith Flex Catheter as the materials and manufacturing processes are equivalent. Test articles met the acceptance criteria.
Simulated Use Testing (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

Test	Test Method Summary	Acceptance Criteria	Conclusions
Labeling Legibility	Label is legible after printing.	Test samples shall demonstrate text legibility.	Test results for the Zenith Flex Catheter (K172167) were leveraged for the subject 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 Flex Catheter (K172167) were leveraged for the subject Zenith Flex as the materials and manufacturing processes are equivalent. Test articles met the acceptance criteria.
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 subject Zenith Flex Catheter is substantially equivalent to the predicate device

Test	Test Method Summary	Acceptance Criteria	Conclusions
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 subject 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 subject Zenith Flex Catheter is substantially equivalent to the predicate device
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 subject 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 subject 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.

Test	Test Method Summary	Acceptance Criteria	Conclusions
Visual Inspection (Aspiration Tubing Set)	Finished Devices were inspected for damage visually	Test samples should meet visual inspection specifications.	Test results for the Zenith Flex Catheter (K172167) were leveraged for the subject Zenith Flex Catheter as the aspiration tubing is the same. Test articles met the acceptance criteria.
Tensile (Aspiration Tubing Set)	Finished devices were elongated until failure	Test sample ultimate tensile strength must meet or exceed existing tensile strength specifications.	Test results for the Zenith Flex Catheter (K172167) were leveraged for the subject Zenith Flex Catheter as the aspiration tubing is the same. Test articles met the acceptance criteria.
Leak – Liquid (Aspiration Tubing Set)	Tubing pressurized with fluid and inspected for leak	Test samples should be within existing Leak – Liquid specifications.	Test results for the Zenith Flex Catheter (K172167) were leveraged for the subject Zenith Flex Catheter as the aspiration tubing is the same. Test articles met the acceptance criteria.
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.	Test results for the Zenith Flex Catheter (K172167) were leveraged for the subject Zenith Flex Catheter as the aspiration tubing is the same. Test articles met the acceptance criteria.
Luer Compatibility (Aspiration Tubing Set)	Testing completed per ISO 80369-7	Hub shall meet existing Luer specifications.	Test results for the Zenith Flex Catheter (K172167) were leveraged for the subject Zenith Flex Catheter as the aspiration tubing is the same. Test articles met the acceptance criteria.

Test	Test Method Summary	Acceptance Criteria	Conclusions
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.	Test results for the Zenith Flex Catheter (K172167) were leveraged for the subject Zenith Flex Catheter as the aspiration tubing is the same. Test articles met the acceptance criteria.
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.	Test results for the Zenith Flex Catheter (K172167) were leveraged for the subject Zenith Flex Catheter as the aspiration tubing is the same. Test articles met the acceptance criteria.
Lumen Patency (Aspiration Tubing Set)	Samples were evaluated for lumen collapse during aspiration	Test sample results must meet or exceed existing lumen patency specifications.	Test results for the Zenith Flex Catheter (K172167) were leveraged for the subject Zenith Flex Catheter as the aspiration tubing is the same. Test articles met the acceptance criteria.
Dimensions (Aspiration Tubing Set)	Critical dimensions were measured.	Test samples should be within existing dimensional specifications.	Test results for the Zenith Flex Catheter (K172167) were leveraged for the subject Zenith Flex Catheter as the aspiration tubing is the same. Test articles met the acceptance criteria.
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	Test results for the Zenith Flex Catheter (K172167) were leveraged for the subject Zenith Flex Catheter as the packaging is the same. Test articles met the acceptance criteria.

Test	Test Method Summary	Acceptance Criteria	Conclusions
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.	Test results for the Zenith Flex Catheter (K172167) were leveraged for the subject Zenith Flex Catheter as the packaging is the same. Test articles met the acceptance criteria.
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.	Test results for the Zenith Flex Catheter (K172167) were leveraged for the subject Zenith Flex Catheter as the aspiration tubing is the same. Test articles met the acceptance criteria.
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.	Test results for the Zenith Flex Catheter (K172167) were leveraged for the subject Zenith Flex Catheter as the aspiration tubing is the same. Test articles met the acceptance criteria.
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.	Test results for the Zenith Flex Catheter (K172167) were leveraged for the subject Zenith Flex Catheter as the aspiration tubing is the same. Test articles met the acceptance criteria.

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 Reference 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.

Summary of Substantial Equivalence

The performance characteristics and the test results demonstrate that the 074 Zenith Flex Catheter meets the acceptance criteria to determine that the 074 Zenith Flex Catheter is substantially equivalent to the predicate device. Furthermore, the intended use, the operating principles, the design, materials and the results of biocompatibility testing, shelf-life, packaging and sterilization processes are all equivalent and support the conclusion that all devices are

technologically similar. Lastly, the review of published clinical data also supports the use of the 074 Zenith Flex Catheter under the NRY product code based on the similar technological characteristics to devices currently available.