August 2, 2019

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

Re: K190338
Trade/Device Name: Zenith Flex Aspiration System (046 Zenith Flex Catheter)
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NRY
Dated: July 3, 2019
Received: July 5, 2019

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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, Ph.D.
Assistant Director
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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)*
K190338

Device Name
Zenith Flex Aspiration System (046 Zenith Flex Catheter)

Indications for Use *(Describe)*
The Zenith Flex Aspiration System, including the 046 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

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Date Prepared

February 12, 2019

Device Trade or Proprietary Name

Zenith Flex Aspiration System (046 Zenith Flex Catheter)

Device Common or Classification Name:

Catheter, Percutaneous, 21 CFR 870.1250, Class II

Product Code:

NRY (Catheter)

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

Name of Predicate Device	Name of Manufacturer	510(k) Number
3 Max	Penumbra	K113163

Identification of the Legally Marketed Device used as the Reference Device

Name of Reference Device	Name of Manufacturer	510(k) Number
Zenith Flex System (071 Zenith Flex)	InNeuroCo, Inc	K172167

Device Description

The InNeuroCo 046 Zenith Flex Catheter is a variable stiffness catheter that has a catheter shaft reinforced with Nitinol to provide support. The proximal section has an embedded nitinol flat wire cross coil that transitions to a nitinol round wire single coil in the distal end. It has a radiopaque Platinum/Iridium marker band on the distal end. The 046 Zenith Flex Catheter is available with an internal diameter of 0.046 inches. The outer diameter is 0.058 inches along the proximal shaft and 0.056 inches at the distal tip. The 046 Zenith Flex Catheter is available in two working lengths: 153 cm, and 160 cm. The 046 Zenith Flex Catheter has a PTFE-lined lumen to reduce friction as it travels over a guidewire. Accessories included with the device are a Tuohy-Borst Hemostasis Valve and peel-away introducer. The 046 Zenith Flex Catheter is supplied sterile, non-pyrogenic, and intended for single use only.

The other system components are: the Aspiration Tubing Set and the VC-701 Cliq Aspirator Pump. The Aspiration Tubing Set is provided sterile and is intended for single use only. The aspiration pump is provided non-sterile and is used in multiple procedures.

Indications for Use

The Zenith Flex Aspiration System, including the 046 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 3 Max	Subject Device InNeuroCo, Inc. 046 Zenith Flex Catheter
510(k) Number	K113163	K190338
Classification	Class II	Same
Product Code	NRY	Same
Review Panel	Neurology	Same
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 (in the internal carotid, middle cerebral – M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset.	The Zenith Flex Aspiration System, including the 046 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 in the catheter package	3Max Reperfusion Catheter,	046 Zenith Flex Catheter, Peel Away Introducer, Hemostasis Valve
System components	Catheter, Pump, Aspiration Tubing	Same
Catheter Shaft Material	Polyether Block Amide (PEBAX), Urethane, Nylon	Same
Inner Liner	PTFE	Same
Hub Material	Polycarbonate	Same
Strain Relief	Stainless Steel	Polyolefin
Catheter Shaft Reinforcement	Stainless Steel/Nitinol	Same

Reinforcement pattern	Coil	Same
Lubricious Coating	Hydrophilic Coating	Same
Radiopaque Marker Band	Platinum/ Iridium	Same
Catheter Packaging	Tyvek/Nylon Pouch, polyethylene support tube, packaging card, carton	Same
Sterilization	Ethylene Oxide	Same
Pyrogenicity	Nonpyrogenic	Same
Working Lengths	153 cm, 160 cm	Same
Inside Diameter (ID)	0.043 in distal 0.035 in proximal	0.046 in
Proximal Outer Diameter	0.062 in	0.058 in
Distal Outer Diameter	0.050 in nominal	0.056 in
Introducer	Peelaway to aid in catheter tip introduction into hemostasis valve	Peelaway to aid in catheter tip introduction into hemostasis valve
Hemostasis Valve	Yes	Same
Luer Tapered Hub	Yes	Same
Aspiration Method	Pump	Same
Aspiration Pressure	20-29 in Hg	22-28 in Hg

The 046 Zenith Flex catheter is very similar to the predicate Penumbra 3Max device. The catheter are built using similar materials – Pebax, Urethane, and Nylon for the shaft with a PTFE liner. Both devices have a stainless steel coil reinforcement for the shaft and have a polycarbonate hub. Each device has a hydrophilic coating with platinum/iridium marker bands for visualization. The 046 Zenith Flex catheter has a polyolefin strain relief compared to a stainless steel for the predicate

device; however, this difference is not significant as the polyolefin strain relief provides the same function, passed all performance testing, and passed the relevant biocompatibility testing.

The sizing of the catheters is also similar. The working lengths are the same for both devices. The proximal and distal OD of 046 Zenith Flex Catheter is 0.058 inches and 0.056 inches, respectively, compared to 0.062 inches proximal OD and 0.050 inches distal OD of the predicate device. The difference in OD is small and the 046 Zenith Flex Catheter has an overall smaller profile when entering the body than the predicate. The inner diameter of the 046 Zenith Flex Catheter is larger than the predicate due to a thinner wall.

Both devices go through EO sterilization and use a pump for aspiration. The 046 Zenith Flex Catheter has a narrower aspiration pressure operation range, but this range is within the predicate's operating pressure range.

Comparison to Reference Device

	Reference Device InNeuroCo, Inc. 071 Zenith Flex	Subject Device InNeuroCo, Inc. 046 Zenith Flex Catheter
510(k) Number	K172167	K190338
Classification	Class II	Same
Product Code	NRY	Same
Review Panel	Neurology	Same
Indications For Use	The Zenith Flex Aspiration 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.	Same
Components Supplied in the catheter package	Zenith Flex Catheter, Peel Away Introducer, Hemostasis Valve, Scout Introducer	046 Zenith Flex Catheter, Peel Away Introducer, Hemostasis Valve

System components	Catheter, Pump, Aspiration Tubing	Same
Catheter Shaft Material	Polyether Block Amide (PEBAX), Urethane, Nylon	Same
Inner Liner	PTFE	Same
Hub Material	Polycarbonate	Same
Strain Relief	Polyolefin	Same
Catheter Shaft Reinforcement	Stainless Steel/Nitinol	Same
Reinforcement pattern	Coil	Same
Lubricious Coating	Hydrophilic Coating	Same
Radiopaque Marker Band	Platinum/ Iridium	Same
Catheter Packaging	Tyvek/Nylon Pouch, polyethylene support tube, packaging card, SBS carton	Same
Sterilization	Ethylene Oxide	Same
Pyrogenicity	Nonpyrogenic	Same
Working Lengths	115, 125, 132 cm	153 cm, 160 cm
Inside Diameter (ID)	0.071 in	0.046 in
Proximal Outer Diameter	0.085 in	0.058 in
Distal Outer Diameter	0.082 in nominal	0.056 in
Introducer	Peelaway to aid in catheter tip introduction into hemostasis valve Scout to help with the navigation	Peelaway to aid in catheter tip introduction into hemostasis valve
Hemostasis Valve	Yes	Same
Luer Tapered Hub	Yes	Same

Aspiration Method	Pump	Same
Aspiration Pressure	22-28 in Hg	Same

Summary of Non-Clinical Data

Biocompatibility tests conducted with the 046 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 046 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 046 Zenith Flex Catheter 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 subject Zenith Flex system and the contralateral side was treated with the 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

To demonstrate substantial equivalence between the subject 046 Zenith Flex Catheter and the reference 071 Zenith Flex Catheter and the predicate Penumbra 3 Max 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 046 Zenith Flex Catheter has similar performance characteristics as

the predicate device and the reference device. All 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 used to support the biocompatibility of 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 used to support the biocompatibility of 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 used to support the biocompatibility of 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	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 used to support the biocompatibility of 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-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 used to support the biocompatibility of 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 used to support the biocompatibility of 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 used to support the biocompatibility of 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 used to support the biocompatibility of 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-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 used to support the biocompatibility of 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-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 used to support the biocompatibility of 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 used to support the material stability of 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 80369	Hub shall meet existing Luer specifications.	Zenith Flex Catheter test samples met the acceptance criteria for hub compatibility to demonstrate that the Zenith Flex Catheter is substantially equivalent to the predicate device.
Diameters (Zenith Flex Catheter)	Testing completed per ISO 10555-1	Test samples should be within existing outside or inside 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.

Test	Test Method Summary	Acceptance Criteria	Conclusions
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.
Particulates (Zenith Flex Catheter)	Samples conditioned in benchtop anatomical model. Testing completed per USP 788 as a guide.	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.

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 used to support this endpoint 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.	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 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 (product label and product peel-away label)	Label is legible after printing.	Test samples shall demonstrate text legibility.	Test results for the Zenith Flex Catheter (K172167) were used to support this assessment of the subject Zenith Flex Catheter as the materials and manufacturing processes are equivalent. Test articles met the acceptance criteria.
Barcode (product label and product peel-away label)	Barcode is readable with a standard barcode reader.	Test samples shall demonstrate readily readable barcodes	Test results for the Zenith Flex Catheter (K172167) were used to support this assessment 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 (The Aspiration Tubing Set is identical to that supplied as part of the cleared Zenith Flex System (K172167)). is substantially equivalent to the predicate device.

Test	Test Method Summary	Acceptance Criteria	Conclusions
Shelf Life (Zenith Flex Catheter & Aspiration Tubing Set)	ASTM F1980	Aged test samples must meet or exceed existing specifications	Zenith Flex Catheter test samples met the acceptance criteria for shelf life. The Aspiration Tubing Set is identical to that supplied as part of the cleared Zenith Flex System (K172167). Therefore, shelf life evaluation for this component was based on completed testing submitted in K172167. Test articles met the acceptance criteria This demonstrates 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
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

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 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.
Visual Inspection (Aspiration Tubing Set)	Finished Devices were inspected for damage visually	Test samples should meet visual inspection specifications.	The Aspiration Tubing Set is identical to that supplied as part of the cleared Zenith Flex System (K172167). Therefore, visual inspection evaluation for this component was based on completed testing submitted in K172167. 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.	The Aspiration Tubing Set is identical to that supplied as part of the cleared Zenith Flex System (K172167). Therefore, tensile evaluation for this component was based on completed testing submitted in K172167. Test articles met the acceptance criteria

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.	The Aspiration Tubing Set is identical to that supplied as part of the cleared Zenith Flex System (K172167). Therefore, leak-liquid evaluation for this component was based on completed testing submitted in K172167. 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.	The Aspiration Tubing Set is identical to that supplied as part of the cleared Zenith Flex System (K172167). Therefore, leak-air, tubing and control switch evaluation for this component was based on completed testing submitted in K172167. Test articles met the acceptance criteria
Luer Compatibility (Aspiration Tubing Set)	Testing completed per ISO 80369-7	Hub shall meet existing Luer specifications.	The Aspiration Tubing Set is identical to that supplied as part of the cleared Zenith Flex System (K172167). Therefore, luer compatibility evaluation for this component was based on completed testing submitted in K172167. Test articles met the acceptance criteria
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.	The Aspiration Tubing Set is identical to that supplied as part of the cleared Zenith Flex System (K172167). Therefore, suction connector separation force evaluation for this component was based on completed testing submitted in K172167. Test articles met the acceptance criteria.

Test	Test Method Summary	Acceptance Criteria	Conclusions
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.	The Aspiration Tubing Set is identical to that supplied as part of the cleared Zenith Flex System (K172167). Therefore, vacuum drop/suction connector secure attachment evaluation for this component was based on completed testing submitted in K172167. 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.	The Aspiration Tubing Set is identical to that supplied as part of the cleared Zenith Flex System (K172167). Therefore, lumen patency evaluation for this component was based on completed testing submitted in K172167. Test articles met the acceptance criteria .
Dimensions (Aspiration Tubing Set)	Critical dimensions were measured.	Test samples should be within existing dimensional specifications.	The Aspiration Tubing Set is identical to that supplied as part of the cleared Zenith Flex System (K172167). Therefore, dimensions evaluation for this component was based on completed testing submitted in K172167. 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	Zenith Flex Catheter test samples met the acceptance criteria for packaging peel to demonstrate that the subject Zenith Flex Catheter is substantially equivalent to the predicate device.

Test	Test Method Summary	Acceptance Criteria	Conclusions
Packaging – Dye Leak (Aspiration Tubing Set)	Testing completed per ASTM F1929-12	Test sample shall not exhibit any visual leaks or channels	The Aspiration Tubing Set is identical to that supplied as part of the cleared Zenith Flex System (K172167). The component is packaged in the same packaging as supplied as part of the cleared Zenith Flex System (K172167). Therefore, packaging – dye leak evaluation for this component was based on completed testing submitted in K172167. 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.	Zenith Flex Catheter test samples met the acceptance criteria for packaging peel to demonstrate that the subject Zenith Flex Catheter is substantially equivalent to the predicate device.
Packaging – Peel (Aspiration Tubing Set)	Testing completed per ASTM F88-09	Test sample tensile strength must meet or exceed existing tensile strength specifications.	The Aspiration Tubing Set is identical to that supplied as part of the cleared Zenith Flex System (K172167). The component is packaged in the same packaging as supplied as part of the cleared Zenith Flex System (K172167). Therefore, packaging – dye leak evaluation for this component was based on completed testing submitted in K172167. Test articles met the acceptance criteria.

Test	Test Method Summary	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.	The Aspiration Tubing Set is identical to that supplied as part of the cleared Zenith Flex System (K172167). Therefore, the biocompatibility evaluation for this component was based on completed testing submitted in K172167. 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.	The Aspiration Tubing Set is identical to that supplied as part of the cleared Zenith Flex System (K172167). Therefore, the biocompatibility evaluation for this component was based on completed testing submitted in K172167. 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.	The Aspiration Tubing Set is identical to that supplied as part of the cleared Zenith Flex System (K172167). Therefore, the biocompatibility evaluation for this component was based on completed testing submitted in K172167. Test articles met the acceptance criteria.
Peel Force (Peel-Away Introducer)	Test samples were pulled to failure	Test sample tensile strength must meet or exceed existing tensile strength specifications.	Test results for the Zenith Flex Catheter (K172167) were used to support this assessment for the subject Zenith Flex Catheter as the Peel-Away Introducer is the same. Test articles met the acceptance criteria.

Test	Test Method Summary	Acceptance Criteria	Conclusions
Unsplit length (Peel-Away Introducer)	Unsplit length of the test samples was measured	Test sample length measurement must meet or exceed existing dimensional specifications.	Test results for the Zenith Flex Catheter (K172167) were used to support this assessment for the subject Zenith Flex Catheter as the Peel-Away Introducer is the same. Test articles met the acceptance criteria.
Diameters (Peel-Away Introducer)	Test samples should be within existing outside or inside diameter specification.	Test sample inside and outside diameter measurement must meet or exceed existing dimensional specifications.	Test results for the Zenith Flex Catheter (K172167) were used to support this assessment for the subject Zenith Flex Catheter as the Peel-Away Introducer is the same. Test articles met the acceptance criteria.
Chemical Compatibility (Hemostasis valve)	Hemostasis valve exposed to chemicals readily available in a clinical setting.	Product shall withstand exposure to chemicals without degradation.	Test results for the Hemostasis valve packaged with Zenith Flex Catheter (K172167) were used to support this assessment for the subject hemostasis valve packaged with Zenith Flex Catheter as the materials are equivalent. Test articles met the acceptance criteria.
Dimensional (Hemostasis valve)	Test samples should be within inside diameter specification.	Test sample inside diameter measurement must meet or exceed existing dimensional specifications.	Test results for the Hemostasis valve packaged with Zenith Flex Catheter (K172167) were used to support this assessment for the subject hemostasis valve packaged with Zenith Flex Catheter as the materials are equivalent. 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 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.

Summary of Substantial Equivalence

The performance characteristics and the test results demonstrate that the 046 Zenith Flex Catheter meets the acceptance criteria to determine that the 046 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 046 Zenith Flex Catheter under the NRY product code based on the similar technological characteristics to devices currently available.