October 19, 2017

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

Re: K171672
Trade/Device Name: Zenith (065 and 074)
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: September 15, 2017
Received: September 18, 2017

Dear Ms. 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Carlos L. Pena -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171672

Device Name
Zenith

Indications for Use *(Describe)*
The Zenith is indicated for the introduction of interventional devices into the peripheral and neuro vasculature.

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

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

Date Prepared

September 14, 2017

Device Trade or Proprietary Name

Zenith
Hemostasis Valve
Split Sheath Introducer
Scout Introducer

Device Common or Classification Name:

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

Product Code:

DQY (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
Navien Intracranial Support Catheter	Medtronic	K110055
INTERMEDIATE CATHETER	InNeuroCo	K152202

Device Description

The InNeuroCo Zenith product consists of a catheter, a hemostasis valve, two split sheath introducers, and a Scout introducer. The Zenith catheter is a single lumen, variable stiffness catheter that has an outer polymer shaft and is reinforced with a Stainless Steel cross coil. The Zenith catheter has a radiopaque Platinum/Iridium marker band on the distal end. The Zenith product line is available in two internal diameters: 0.065 inches and 0.074 inches. The 0.065 catheter has a tapered design and is 0.079 inches outer diameter in the distal end and a 0.081 inches outer diameter in the proximal end. The 0.074 catheter has a nominal outer diameter of 0.086 inches. There are three working lengths available: 115 cm, 125 cm, and 132 cm in either diameter. The Zenith catheter has a PTFE-lined lumen throughout the catheter shaft. The catheter is flexible and has a hydrophilic coating. The Zenith catheter is inserted through a guide catheter or vascular sheath, provides access to the target site, and once in place, provides a reinforcing conduit for other intravascular devices. Accessories included with the device are a Tuohy-Borst hemostasis valve with an extension luer and two split sheath introducers. There is another introducer, named Scout, which provides support to the Zenith catheter while tracking to target site. The Zenith product line is supplied sterile, non-pyrogenic, and intended for single use only.

Indications for Use

The Zenith is indicated for the introduction of interventional devices into the peripheral and neuro vasculature.

Comparison to Predicate Device

	Predicate Device Medtronic Navien	**InNeuroCo, Inc. Zenith**	**Reference Device InNeuroCo IC**
510(k) Number	K110055	K171672	K152202
Classification	21CFR870.1250, Class II	21CFR870.1250, Class II	21CFR870.1250, Class II
Product Code	DQY	DQY	DQY
Review Panel	Cardiovascular	Cardiovascular	Cardiovascular
Indications For Use	The Navien Intracranial Support Catheter is indicated for the introduction of interventional devices into the peripheral and neuro vasculature.	The Zenith is indicated for the introduction of interventional devices into the peripheral and neuro vasculature.	The Intermediate Catheter is indicated for the introduction of interventional devices into the peripheral and neuro vasculature.
Components Supplied	Navien Catheter, Introducer Sheath	Zenith Catheter, Peel Away Introducers, Hemostasis Valve, Scout Introducer	Intermediate Catheter, Peel Away Introducer, Hemostasis Valve,
Catheter Shaft Material	Polymeric Catheter	Polymeric Catheter	Polymeric Catheter
Inner Liner	PTFE	PTFE	PTFE
Catheter Shaft Reinforcement	Nitinol	Stainless Steel	Stainless Steel/Nitinol
Reinforcement pattern	Coil	Cross Coil	Braid

	Predicate Device Medtronic Navien		**InNeuroCo, Inc. Zenith**		**Reference Device InNeuroCo IC**
Lubricious Coating	Hydrophilic Coating		Hydrophilic Coating		Hydrophilic Coating
Radiopaque Marker Band	Platinum/ Iridium		Platinum/ Iridium		Platinum/ Iridium
Packaging	PET/PE/Tyvek Pouch, Hoop, packaging card, SBS carton		Tyvek/Nylon Pouch, polyethylene support tube, packaging card, SBS carton		Tyvek/Nylon Pouch, polyethylene support tube, packaging card, SBS carton
Working Lengths	105,115, 125, 130		115, 125, 132 cm		105, 115, 125 cm
Proximal Internal Diameter (ID)	Navien 058	0.058 inches	Zenith 0.065	0.065 inches	0.062 inches proximal
	Navien 072	0.072 inches	Zenith 0.074	0.074 inches	
Distal ID	Navien 058	0.058 inches	Zenith 0.065	0.065 inches	0.060 inches distal
	Navien 072	0.072 inches	Zenith 0.074	0.074 inches	
Proximal Outer Diameter	Navien 058	0.070 inches	Zenith 0.065	0.081 inches	0.079 inches
	Navien 072	0.084 inches	Zenith 0.074	0.086 inches	
Distal Outer Diameter	Navien 058	0.070 inches	Zenith 0.065	0.079 inches	0.072
	Navien 072	0.084 inches	Zenith 0.074	0.086 inches	
Peel Away Introducer	Aid in catheter tip introduction into hemostasis valve		Aid in catheter tip introduction into hemostasis valve		Aid in catheter tip introduction into hemostasis valve

	Predicate Device Medtronic Navien	InNeuroCo, Inc. Zenith	Reference Device InNeuroCo IC
Hemostasis Valve	N/A	Minimizes blood loss	Minimizes blood loss
Luer Tapered Hub	Yes	Yes	Yes
Compatible Guidewire	0.038	0.038 inches	0.038 inches
Scout Introducer	No	Yes	No
Sterilization	EO SAL 10^{-6}	EO SAL 10^{-6}	EO SAL 10^{-6}
Pyrogenicity	Nonpyrogenic	Nonpyrogenic	Nonpyrogenic
Biocompatibility	Meets ISO 10993-1:2009	Meets ISO 10993-1:2009	Meets ISO 10993-1:2009

Summary of Non-Clinical Data

Biocompatibility tests conducted with the Zenith 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 21 CFR 58, Good Laboratory Practices. Biocompatibility testing found the Zenith to be biocompatible and non-pyrogenic.

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

Zenith Performance Testing

Test	Test Method Summary	Acceptance Criteria	Conclusions	Predicate Device Testing (Yes/Unknown)
Biocompatibility-Material Mediated Pyrogen	Testing completed per ISO 10993-11	The test article extracts must not cause a febrile reaction greater	Zenith test samples met the acceptance criteria for Material Mediated Pyrogen	Yes

Test	Test Method Summary	Acceptance Criteria	Conclusions	Predicate Device Testing (Yes/Unknown)
		than 0.5°C in any individual subject.	to demonstrate that the Zenith is substantially equivalent to the predicate device.	
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.	Zenith test samples met the acceptance criteria for Cytotoxicity MEM Elution to demonstrate that the Zenith is substantially equivalent to the predicate device.	Yes
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%.	Zenith test samples met the acceptance criteria for Hemolysis ASTM Method, extract human blood to demonstrate that the Zenith is substantially equivalent to the predicate device.	Yes
Biocompatibility-Hemolysis, ASTM method, direct contact (human blood)	Testing completed per ISO 10993-4	The hemolytic index above the negative control article must be less than 5%.	Zenith test samples met the acceptance criteria for Hemolysis, ASTM method, direct contact (human blood) to demonstrate that the Zenith is substantially	Yes

Test	Test Method Summary	Acceptance Criteria	Conclusions	Predicate Device Testing (Yes/Unknown)
			equivalent to the predicate device.	
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.	Zenith test samples met the acceptance criteria for Unactivated Partial Thromboplastin Time to demonstrate that the Zenith is substantially equivalent to the predicate device.	Yes
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.	Zenith test samples met the acceptance criteria for Complement Activation to demonstrate that the Zenith is substantially equivalent to the predicate device.	Yes
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.	Zenith test samples met the acceptance criteria for Dog Thromboresistance to demonstrate that the Zenith is substantially equivalent to the predicate device.	Yes
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.	Zenith test samples met the acceptance criteria for Maximization Sensitization to	Yes

Test	Test Method Summary	Acceptance Criteria	Conclusions	Predicate Device Testing (Yes/Unknown)
			demonstrate that the Zenith is substantially equivalent to the predicate device.	
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.	Zenith test samples met the acceptance criteria for Intracutaneous Toxicity/Reactivity to demonstrate that the Zenith is substantially equivalent to the predicate device.	Yes
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.	Zenith test samples met the acceptance criteria for Acute Systemic Toxicity Test to demonstrate that the Zenith is substantially equivalent to the predicate device.	Yes
Animal Testing-Angiographic Evaluation	Product evaluated within a porcine model for clinically significant injury.	No units tested can cause vessel injury.	Zenith test samples met the acceptance criteria for Animal Testing-Angiographic Evaluation to demonstrate that the Zenith is substantially equivalent to the predicate device.	Yes
Chemical Compatibility	Catheter exposed to	Chemicals have no negative effect on	Zenith test samples met the acceptance	Unknown

Test	Test Method Summary	Acceptance Criteria	Conclusions	Predicate Device Testing (Yes/Unknown)
	chemicals readily available in a clinical setting.	the catheter or accessories.	criteria for Chemical Compatibility to demonstrate that the Zenith is substantially equivalent to the predicate device.	
Radiographic Detectability	Testing completed per ISO 10555-1	Product shall be visible under fluoro imaging.	Zenith test samples met the acceptance criteria for Radiographic Detectability to demonstrate that the Zenith is substantially equivalent to the predicate device.	Yes – part of *in vivo* testing
Visual Inspection	Testing completed per ISO 10555-1	Catheter shall appear free from damage, including a rounded tip and smooth transition points.	Zenith test samples met the acceptance criteria for Visual Inspection to demonstrate that the Zenith is substantially equivalent to the predicate device.	Yes
Working Length	Testing completed per ISO 10555-1	Test samples should be within existing working length specification.	Zenith test samples met the acceptance criteria for Working Length to demonstrate that the Zenith is substantially equivalent to the predicate device.	Yes

Test	Test Method Summary	Acceptance Criteria	Conclusions	Predicate Device Testing (Yes/Unknown)
Hub compatibility	Testing completed per ISO 594-1 and ISO 594-2	Hub shall meet existing Luer specifications.	Zenith test samples met the acceptance criteria for Hub compatibility to demonstrate that the Zenith is substantially equivalent to the predicate device.	Yes
Outside diameter	Testing completed per ISO 10555-1	Test samples should be within existing outside diameter specification.	Zenith test samples met the acceptance criteria for Outside diameter to demonstrate that the Zenith is substantially equivalent to the predicate device.	Yes
Leak – Air	Testing completed per ISO 10555-1	Test samples should be within existing Air – Leak specifications.	Zenith test samples met the acceptance criteria for Leak – Air to demonstrate that the Zenith is substantially equivalent to the predicate device.	Yes
Leak – Liquid	Testing completed per ISO 10555-1	Test samples should be within existing Leak – Liquid specifications.	Zenith test samples met the acceptance criteria for Leak – Liquid to demonstrate that the Zenith is substantially	Yes

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

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

Test	Test Method Summary	Acceptance Criteria	Conclusions	Predicate Device Testing (Yes/Unknown)
	diameters until kink is observed.	Resistance specifications.	demonstrate that the Zenith is substantially equivalent to the predicate device.	
Torque	Conditioned samples are torqued to failure	Test sample torque results must meet or exceed existing torque specifications.	Zenith test samples met the acceptance criteria for Torque to demonstrate that the Zenith is substantially equivalent to the predicate device.	Yes
PTFE Liner inspection	Zenith was challenged to demonstrate liner adherence.	Test sample liner adhesion must meet or exceed existing PTFE Liner inspection specifications.	Zenith test samples met the acceptance criteria for PTFE Liner inspection to demonstrate that the Zenith is substantially equivalent to the predicate device.	Unknown
Hydrophilic Coating Integrity	Conditioned samples were repeatedly exposed to friction to demonstrate that the hydrophilic coating is not affected.	Test sample results must meet or exceed existing Hydrophilic Coating Integrity specifications.	Zenith test samples met the acceptance criteria for Hydrophilic Coating Integrity to demonstrate that the Zenith is substantially equivalent to the predicate device.	Unknown
Labeling Legibility	Label is legible after printing.	Test samples shall demonstrate text legibility.	Zenith test samples met the acceptance criteria for labeling legibility to demonstrate that	Unknown

Test	Test Method Summary	Acceptance Criteria	Conclusions	Predicate Device Testing (Yes/Unknown)
			the Zenith is substantially equivalent to the predicate device.	
Barcode	Barcode is readable with a standard barcode reader.	Test samples shall demonstrate readily readable barcodes	Zenith test samples met the acceptance criteria for barcode testing to demonstrate that the Zenith is substantially equivalent to the predicate device.	Unknown
Sterilization	ISO 11135 and AAMI TIR 28	Sterilization load shall pose an equal or lesser challenge to sterilize than existing sterile product loads.	Zenith sterilization load met the acceptance criteria for sterilization to demonstrate that the Zenith is substantially equivalent to the predicate device.	Yes
Shelf Life	ASTM F1980	Aged test samples must meet or exceed existing specifications	Zenith test samples met the acceptance criteria for shelf life to demonstrate that the Zenith is substantially equivalent to the predicate device.	Yes