January 26, 2018

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

Re: K173709
Trade/Device Name: Zenith Support Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY, DTL, DYB
Dated: January 4, 2018
Received: January 5, 2018

Dear Marianne Grunwaldt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

William J. Heetderks -A
2018.01.26 16:50:00 -05'00'

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)*
K173709

Device Name
Zenith Support Catheter

Indications for Use *(Describe)*
The Zenith Support Catheter 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.

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510(K) SUMMARY

ADMINISTRATIVE INFORMATION

Date of Summary Preparation: December 1st, 2017

CONTACT INFORMATION

Submitter/Manufacturer

InNeuroCo Inc
4635 NW 103rd Avenue
Sunrise, Florida 33351
Tel: 1-954-742-5988
Fax: 1-954-742-5989

Primary Submission Contact

Marianne Grunwaldt
Cell:1-305-495-3883
Fax: 1-954-742-5988
Email: Marianne@InNeuroCo.com

Secondary Submission Contact

Ming Cheng Chew
Regulatory Consultant, Libra Medical, Inc.
8401 73rd Ave North, Suite 63
Brooklyn Park, MN 55428
Cell: 763-232-3701
Fax: 763-477-6357
Email: mcchew@libramed.com

DEVICE INFORMATION

Device Trade or Proprietary Name
Zenith Support Catheter

Device Common or Classification Name:
Catheter, Percutaneous, 21 CFR 870.1250, Class II
Hemostasis Valve, 21 CFR 870.4290, Class II
Catheter Introducer, 21 CFR 870.1340, Class II

Product Code:
DQY (Catheter)
DTL (Hemostasis Valve)
DYB (Catheter Introducer)

IDENTIFICATION OF THE LEGALLY MARKETED DEVICE TO WHICH EQUIVALENCE IS BEING CLAIMED

Name of Predicate Device	Name of Manufacturer	510(k) Number
Zenith 074	InNeuroCo	K171672

DEVICE DESCRIPTION

The InNeuroCo Zenith Support product consists of a catheter, a hemostasis valve, and a split sheath introducer. The Zenith Support 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 Support catheter has a radiopaque Platinum/Iridium marker band on the distal end. The Zenith Support is available with an internal diameter of 0.074 inches and a nominal outer diameter of 0.086 inches. There are three working lengths available: 95 cm, 105 cm, and 115 cm in either diameter. The Zenith Support catheter has a PTFE-lined lumen throughout the catheter shaft. The catheter is flexible and has a hydrophilic coating. The Zenith Support 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 a split sheath introducer. The Zenith product line is supplied sterile, non-pyrogenic, and intended for single use only.

INDICATIONS FOR USE / INTENDED USE

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

COMPARISON TO THE PREDICATE DEVICE

	Predicate Device InNeuroCo, Inc. Zenith 074	**Reference Device InNeuroCo SDA**	**InNeuroCo, Inc. Zenith Support**
510(k) Number	K171672	K161262	K173709
Classification	21CFR870.1250, Class II	21CFR870.1250, Class II	21CFR870.1250, Class II
Product Code	DQY	DQY	DQY
Review Panel	Cardiovascular	Cardiovascular	Cardiovascular

	Predicate Device InNeuroCo, Inc. Zenith 074	Reference Device InNeuroCo SDA	InNeuroCo, Inc. Zenith Support
Indications For Use	The Zenith is indicated for the introduction of interventional devices into the peripheral and neuro vasculature.	The Super Distal Access (SDA) is indicated for the introduction of interventional devices into the peripheral and neuro vasculature.	The Zenith Support Catheter is indicated for the introduction of interventional devices into the peripheral and neuro vasculature.
Components Supplied	Zenith Catheter, Peel Away Introducers, Hemostasis Valve, Scout Introducer	Catheter, Peel Away Introducer, Hemostasis Valve,	Zenith Support Catheter, Peel Away Introducer, Hemostasis Valve
Catheter Shaft Material	Polymeric Catheter	Polymeric Catheter	Polymeric Catheter
Inner Liner	PTFE	PTFE	PTFE
Catheter Shaft Reinforcement	Stainless Steel	Stainless Steel/Nitinol	Stainless Steel
Reinforcement pattern	Cross Coil	Braid	Cross Coil
Lubricious Coating	Hydrophilic Coating	Hydrophilic Coating	Hydrophilic Coating
Radiopaque Marker Band	Platinum/ Iridium	Platinum/ Iridium	Platinum/ Iridium
Packaging	Tyvek/Nylon Pouch, polyethylene support tube, 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	115, 125, 132 cm	105, 115, 125 cm	95, 105, 115 cm

	Predicate Device InNeuroCo, Inc. Zenith 074	Reference Device InNeuroCo SDA	InNeuroCo, Inc. Zenith Support
Proximal Internal Diameter (ID)	0.074 inches	0.062 inches	0.074 inches
Distal ID	0.074 inches	0.060 inches distal	0.074 inches
Proximal Outer Diameter	0.086 inches	0.079 inches	0.086 inches
Distal Outer Diameter	0.086 inches	0.072	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
Hemostasis Valve	Minimizes blood loss	Minimizes blood loss	Minimizes blood loss
Luer Tapered Hub	Yes	Yes	Yes
Compatible Guidewire	0.038 inches	0.038 inches	0.038 inches
Scout Introducer	Yes	No	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

Each non-clinical test was analyzed to determine whether or not re-testing should be conducted for the Zenith Support Catheter. The results of the analysis and re-testing showed that the Zenith Support Catheter is substantially equivalent to the predicate device.

Table 1: Non-Clinical Testing Analysis

Test	Test Method Summary	Acceptance Criteria	Re-Tested?	Analysis
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.	Testing was not repeated for the Zenith Support Catheter	There are no material changes from the predicate device. Manufacturing process is identical to the predicate. Only the segment lengths were changed and pitch adjustments were within the predicate device's tolerance
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.	Testing was not repeated for the Zenith Support Catheter	There are no material changes from the predicate device. Manufacturing process is identical to the predicate. Only the segment lengths were changed and pitch adjustments were within the predicate device's tolerance
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%.	Testing was not repeated for the Zenith Support Catheter	There are no material changes from the predicate device. Manufacturing process is identical to the predicate. Only the segment lengths were changed and pitch adjustments were within the predicate device's tolerance
Biocompatibility-Hemolysis, ASTM method,	Testing completed per ISO 10993-4	The hemolytic index above the negative control	Testing was not repeated for the Zenith Support Catheter	There are no material changes from the predicate device.

Test	Test Method Summary	Acceptance Criteria	Re-Tested?	Analysis
direct contact (human blood)		article must be less than 5%.		Manufacturing process is identical to the predicate. Only the segment lengths were changed and pitch adjustments were within the predicate device's tolerance
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.	Testing was not repeated for the Zenith Support Catheter	There are no material changes from the predicate device. Manufacturing process is identical to the predicate. Only the segment lengths were changed and pitch adjustments were within the predicate device's tolerance
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.	Testing was not repeated for the Zenith Support Catheter	There are no material changes from the predicate device. Manufacturing process is identical to the predicate. Only the segment lengths were changed and pitch adjustments were within the predicate device's tolerance
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.	Testing was not repeated for the Zenith Support Catheter	There are no material changes from the predicate device. Manufacturing process is identical to the predicate. Only the segment lengths were

Test	Test Method Summary	Acceptance Criteria	Re-Tested?	Analysis
				changed and pitch adjustments were within the predicate device's tolerance
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.	Testing was not repeated for the Zenith Support Catheter	There are no material changes from the predicate device. Manufacturing process is identical to the predicate. Only the segment lengths were changed and pitch adjustments were within the predicate device's tolerance
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.	Testing was not repeated for the Zenith Support Catheter	There are no material changes from the predicate device. Manufacturing process is identical to the predicate. Only the segment lengths were changed and pitch adjustments were within the predicate device's tolerance
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.	Testing was not repeated for the Zenith Support Catheter	There are no material changes from the predicate device. Manufacturing process is identical to the predicate. Only the segment lengths were changed and pitch adjustments were within the predicate device's tolerance

Test	Test Method Summary	Acceptance Criteria	Re-Tested?	Analysis
Animal Testing-Angiographic Evaluation	Product evaluated within a porcine model for clinically significant injury.	No units tested can cause vessel injury.	Testing was not repeated for the Zenith Support Catheter	The tips, materials, and transitions are identical to the predicate, and the initial evaluation for the predicate included the use of the device without the Scout Introducer
Chemical Compatibility	Catheter exposed to chemicals readily available in a clinical setting.	Chemicals have no negative effect on the catheter or accessories.	Testing was not repeated for the Zenith Support Catheter	There are no material changes from the predicate device, and pitch adjustments are within the tolerance of the predicate device
Radiographic Detectability	Testing completed per ISO 10555-1	Product shall be visible under fluoro imaging.	Testing was not repeated for the Zenith Support Catheter	The marker bands are identical to the predicate
Visual Inspection	Testing completed per ISO 10555-1	Catheter shall appear free from damage, including a rounded tip and smooth transition points.	Testing was not repeated for the Zenith Support Catheter	There are no material changes from the predicate device, and pitch adjustments are within the tolerance of the predicate device
Working Length	Testing completed per ISO 10555-1	Test samples should be within existing working length specification.	Testing was not repeated for the Zenith Support Catheter	The segment lengths do not impact the cut to length step in addition the working length test compares the output to the target length
Hub compatibility	Testing completed per ISO 594-1 and ISO 594-2	Hub shall meet existing Luer specifications.	Testing was not repeated for the Zenith Support Catheter	The hub is identical to the predicate device
Outside diameter	Testing completed per ISO 10555-1	Test samples should be within existing outside	Testing was not repeated for the Zenith Support Catheter	OD is unaffected by the working length change

Test	Test Method Summary	Acceptance Criteria	Re-Tested?	Analysis
		diameter specification.		
Leak – Air	Testing completed per ISO 10555-1	Test samples should be within existing Air – Leak specifications.	Testing was not repeated for the Zenith Support Catheter	There are no material changes from the predicate device, and pitch adjustments are within the tolerance of the predicate device
Leak – Liquid	Testing completed per ISO 10555-1	Test samples should be within existing Leak – Liquid specifications.	Testing was not repeated for the Zenith Support Catheter	There are no material changes from the predicate device, and pitch adjustments are within the tolerance of the predicate device
Particulates	Testing completed per USP 788	Test samples should be within existing Particulate specifications.	Testing was not repeated for the Zenith Support Catheter	There are no material changes from the predicate device, and pitch adjustments are within the tolerance of the predicate device
Simulated Use - Bench	Zenith underwent simulated use testing by a physician in a benchtop model	Test samples must meet predetermined user needs	Yes	Zenith Support Catheter test samples met the acceptance criteria for Simulated Use-Bench to demonstrate that it is substantially equivalent to the predicate device
Catheter Burst	Testing completed per ISO 10555-1	Test sample burst pressures must meet or exceed existing minimum burst pressure specification.	Testing was not repeated for the Zenith Support Catheter.	There are no material changes from the predicate device, and pitch adjustments are within the tolerance of the predicate device

Test	Test Method Summary	Acceptance Criteria	Re-Tested?	Analysis
Tensile	Testing completed per ISO 10555-1	Test sample ultimate tensile strength must meet or exceed existing tensile strength specifications.	Testing was not repeated for the Zenith Support Catheter	The bonds and joints are the same as the predicate Zenith 074 device. Any pitch adjustments are within the tolerance of the predicate device.
Corrosion	Testing completed per ISO 10555-1	Test samples shall exhibit no evidence of corrosion.	Testing was not repeated for the Zenith Support Catheter	There are no material changes from the predicate device, and pitch adjustments are within the tolerance of the predicate device
Packaging – Dye Leak	Testing completed per ASTM F1929-12	Test sample shall not exhibit any visual leaks or channels	Testing was not repeated for the Zenith Support Catheter	The packaging is identical to the cleared reference SDA device
Packaging – Peel	Testing completed per ASTM F88-09	Test sample tensile strength must meet or exceed existing tensile strength specifications.	Testing was not repeated for the Zenith Support Catheter	The packaging is identical to the cleared reference SDA device
Kink Resistance	Samples are subjected to different diameters until kink is observed.	Test sample kink resistance must meet or exceed existing Kink Resistance specifications.	Testing was not repeated for the Zenith Support Catheter	All transitions are the same, only the location of the transition changes, in addition, the pitch adjustments are within the Zenith 074 tolerance
Torque	Conditioned samples are torqued to failure	Test sample torque results must meet or exceed existing torque specifications.	Testing was not repeated for the Zenith Support Catheter	There are no material changes from the predicate device, and pitch adjustments are within the tolerance of the predicate device
PTFE Liner inspection	Zenith was challenged to	Test sample liner adhesion must	Testing was not repeated for the	There are no material changes

Test	Test Method Summary	Acceptance Criteria	Re-Tested?	Analysis
	demonstrate liner adherence.	meet or exceed existing PTFE Liner inspection specifications.	Zenith Support Catheter	from the predicate device, and pitch adjustments are within the tolerance of the predicate device
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.	Testing was not repeated for the Zenith Support Catheter	There are no material changes from the predicate device, and pitch adjustments are within the tolerance of the predicate device
Labeling Legibility	Label is legible after printing.	Test samples shall demonstrate text legibility.	Testing was not repeated for the Zenith Support Catheter substantially equivalent to the predicate device.	The label is almost identical to the predicate device, except that the Scout Introducer is removed from the labeling
Barcode	Barcode is readable with a standard barcode reader.	Test samples shall demonstrate readily readable barcodes	Testing was not repeated for the Zenith Support Catheter	Barcodes are similar to the predicate
Sterilization	ISO 11135 and AAMI TIR 28	Sterilization load shall pose an equal or lesser challenge to sterilize than existing sterile product loads.	Testing was not repeated for the Zenith Support Catheter	The Zenith Support Catheter was adopted into the Zenith Family Sterilization Cycle
Shelf Life	ASTM F1980	Aged test samples must meet or exceed existing specifications	Testing was not repeated for the Zenith Support Catheter	There are no material changes from the predicate device, therefore shelf life testing conducted for the Zenith 074 still applies