DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 19, 2016

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

Re: K161262
Trade/Device Name: Super Distal Access (SDA)
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY, DTL
Dated: August 15, 2016
Received: August 17, 2016

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 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 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 yours,

Michael J. Hoffmann -A

for Carlos L. Peña, Ph.D., M.S.
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)*
K161262

Device Name
Super Distal Access (SDA)

Indications for Use *(Describe)*
The Super Distal Access (SDA) 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

Submitter's Name and Address

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Date Prepared

September 16, 2016

Device Trade or Proprietary Name

Super Distal Access (SDA)

Device Common or Classification Name:

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

Product Code:

DQY(Catheter)
DTL (Hemostasis Valve)

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

Name of Predicate Device	Name of Manufacturer	510(k) Number
INTERMEDIATE CATHETER	InNeuroCo	K152202

Device Description

The Super Distal Access (SDA) is a single lumen, variable stiffness catheter and has a shaft reinforced with a Stainless Steel/Nitinol coil. The SDA has a radiopaque Platinum/Iridium marker band on the distal end. The catheter has a maximum outer diameter of 0.084 inches. It has a tapered design that includes a nominal inner diameter of 0.062 inches in the distal end and 0.068 inches in the proximal end. There are three working lengths available: 115 cm, 125 cm, and 135 cm. The Super Distal Access has a PTFE-lined lumen in the distal end and a Polyimide/PTFE-lined lumen in the proximal end. The catheter is flexible and has a hydrophilic coating. The SDA 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 SDA is supplied sterile, non-pyrogenic, and intended for single use only.

Indications for Use

The Super Distal Access (SDA) is indicated for the introduction of interventional devices into the peripheral and neuro vasculature.

Comparison to Predicate Device

	Predicate Device InNeuroCo, Inc. Intermediate Catheter	InNeuroCo, Inc. Super Distal Access
510(k) Number	K152202	K161262
Classification	21CFR870.1250, Class II	21CFR870.1250, Class II
Product Code	DQY	DQY
Review Panel	Cardiovascular	Cardiovascular
Indication For Use	The Intermediate Catheter 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.
Components Supplied	Catheter, Peel Away Introducer, Hemostasis Valve	Catheter, Peel Away Introducer, Hemostasis Valve
Catheter Shaft Material	Polyimide, Polyether Block Amide (PEBAX), PET, Polycarbonate/Urethane, Nylon	Polyimide, Polyether Block Amide (PEBAX), PET, Polycarbonate/Urethane
Inner Liner	PTFE	Distal: PTFE Proximal: PTFE/Polyimide
Hub Material	Polycarbonate	Polycarbonate
Strain Relief	Polyolefin	Polyolefin
Catheter Shaft Reinforcement	Stainless Steel/Nitinol	Stainless Steel/Nitinol
Lubricious Coating	Hydrophilic Coating	Hydrophilic Coating
Radiopaque Marker Band	Platinum/ Iridium	Platinum/ Iridium
Packaging	Tyvek/Nylon Pouch, polyethylene support hoop, packaging card, SBS Carton	Tyvek/Nylon Pouch, polyethylene support hoop, packaging card, SBS Carton

	Predicate Device InNeuroCo, Inc. Intermediate Catheter	InNeuroCo, Inc. Super Distal Access
Sterilization	Ethylene Oxide	Ethylene Oxide
Pyrogenicity	Nonpyrogenic	Nonpyrogenic
Working Lengths	105, 115, 125 cm	115, 125, 135 cm
Compatible Guidewire	0.038 inches	0.038 inches
Internal Diameter	0.060 inches distal 0.062 inches proximal	0.062 inches distal 0.068 inches proximal
Proximal Outer Diameter	0.079 inches	0.084 inches
Distal Outer Diameter	0.072 inches	0.078 inches
Shelf Life	3 years	3 years
Split Sheath Introducer	Aid in catheter introduction during procedure	Aid in catheter introduction during procedure
Hemostasis Valve	Minimizes blood loss	Minimizes blood loss
Luer Tapered Hub	Yes	Yes

Summary of Non Clinical Data

Biocompatibility tests conducted with the Super Distal Access (SDA) 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 Super Distal Access and its accessories to be biocompatible and non-pyrogenic.

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

Super Distal Access Performance Testing

Test	Test Method Summary	Acceptance Criteria	Conclusions
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.	SDA test samples met the acceptance criteria for Material Mediated Pyrogen to demonstrate that the SDA 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.	SDA test samples met the acceptance criteria for Cytotoxicity MEM Elution to demonstrate that the SDA is substantially equivalent to the predicate device.
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%.	SDA test samples met the acceptance criteria for Hemolysis ASTM Method, extract human blood to demonstrate that the SDA is substantially equivalent to the predicate device.
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%.	SDA test samples met the acceptance criteria for Hemolysis, ASTM method, direct contact (human blood) to demonstrate that the SDA is substantially 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.	SDA test samples met the acceptance criteria for Unactivated Partial Thromboplastin Time to demonstrate that the SDA is substantially equivalent to the predicate device.

Test	Test Method Summary	Acceptance Criteria	Conclusions
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.	SDA test samples met the acceptance criteria for Complement Activation to demonstrate that the SDA is substantially equivalent to the predicate device.
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.	SDA test samples met the acceptance criteria for Dog Thromboresistance to demonstrate that the SDA is substantially equivalent to the predicate device.
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.	SDA test samples met the acceptance criteria for Maximization Sensitization to demonstrate that the SDA 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.	SDA test samples met the acceptance criteria for Intracutaneous Toxicity/Reactivity to demonstrate that the SDA is substantially equivalent to the predicate device.
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.	SDA test samples met the acceptance criteria for Acute Systemic Toxicity Test to demonstrate that the SDA is substantially equivalent to the predicate device.

Test	Test Method Summary	Acceptance Criteria	Conclusions
Animal Testing-Angiographic Evaluation	Product evaluated within a porcine model for clinically significant injury.	No units tested can cause vessel injury.	SDA test samples met the acceptance criteria for Animal Testing-Angiographic Evaluation to demonstrate that the SDA is substantially equivalent to the predicate device.
Chemical Compatibility	Catheter exposed to chemicals readily available in a clinical setting.	Chemicals have no negative effect on the catheter or accessories.	SDA test samples met the acceptance criteria for Chemical Compatibility to demonstrate that the SDA is substantially equivalent to the predicate device.
Radiographic Detectability	Testing completed per ISO 10555-1	Product shall be visible under fluoro imaging.	SDA test samples met the acceptance criteria for Radiographic Detectability to demonstrate that the SDA is substantially equivalent to the predicate device.
Visual Inspection	Testing completed per ISO 10555-1	Catheter shall appear free from damage, including a rounded tip and smooth transition points.	SDA test samples met the acceptance criteria for Visual Inspection to demonstrate that the SDA is substantially equivalent to the predicate device.
Working Length	Testing completed per ISO 10555-1	Test samples should be within existing working length specification.	SDA test samples met the acceptance criteria for Working Length to demonstrate that the SDA is substantially equivalent to the predicate device.

Test	Test Method Summary	Acceptance Criteria	Conclusions
Hub compatibility	Testing completed per ISO 594-1 and ISO 594-2	Hub shall meet existing Luer specifications.	SDA test samples met the acceptance criteria for Hub compatibility to demonstrate that the SDA is substantially equivalent to the predicate device.
Outside diameter	Testing completed per ISO 10555-1	Test samples should be within existing outside diameter specification.	SDA test samples met the acceptance criteria for Outside diameter to demonstrate that the SDA is substantially equivalent to the predicate device.
Leak – Air	Testing completed per ISO 10555-1	Test samples should be within existing Air – Leak specifications.	SDA test samples met the acceptance criteria for Leak – Air to demonstrate that the SDA is substantially equivalent to the predicate device.
Leak – Liquid	Testing completed per ISO 10555-1	Test samples should be within existing Leak – Liquid specifications.	SDA test samples met the acceptance criteria for Leak – Liquid to demonstrate that the SDA is substantially equivalent to the predicate device.
Particulates	Testing completed per USP 788	Test samples should be within existing Particulate specifications.	SDA test samples met the acceptance criteria for Particulates to demonstrate that the SDA is substantially equivalent to the predicate device.
Simulated Use - Bench	SDA underwent simulated use testing by a physician in a benchtop model	Test samples must meet predetermined user needs	SDA test samples met the acceptance criteria for Simulated Use - Bench to demonstrate that the SDA

Test	Test Method Summary	Acceptance Criteria	Conclusions
			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.	SDA test samples met the acceptance criteria for Catheter Burst to demonstrate that the SDA is substantially equivalent to the predicate device.
Tensile	Testing completed per ISO 10555-1	Test sample ultimate tensile strength must meet or exceed existing tensile strength specifications.	SDA test samples met the acceptance criteria for Tensile to demonstrate that the SDA 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 SDA as the materials and manufacturing processes are equivalent.
Packaging – Dye Leak	Testing completed per ASTM F1929-12	Test sample shall not exhibit any visual leaks or channels	Test results for the predicate device were leveraged for the SDA as the materials and manufacturing processes are equivalent.
Packaging – Peel	Testing completed per ASTM F88-09	Test sample tensile strength must meet or exceed existing tensile strength specifications.	Test results for the predicate device were leveraged for the SDA as the materials and manufacturing processes are equivalent.

Test	Test Method Summary	Acceptance Criteria	Conclusions
Kink Resistance	Samples are subjected to different diameters until kink is observed.	Test sample kink resistance must meet or exceed existing Kink Resistance specifications.	SDA test samples met the acceptance criteria for Kink Resistance to demonstrate that the SDA 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.	SDA test samples met the acceptance criteria for Torque to demonstrate that the SDA is substantially equivalent to the predicate device.
PTFE Liner inspection	SDA was challenged to demonstrate liner adherence.	Test sample liner adhesion must meet or exceed existing PTFE Liner inspection specifications.	SDA test samples met the acceptance criteria for PTFE Liner inspection to demonstrate that the SDA is substantially equivalent to 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.	SDA test samples met the acceptance criteria for Hydrophilic Coating Integrity to demonstrate that the SDA is substantially equivalent to the predicate device.
Labeling Legibility	Label is legible after printing.	Test samples shall demonstrate text legibility.	SDA test samples met the acceptance criteria for labeling legibility to demonstrate that the SDA is substantially equivalent to the predicate device.
Barcode	Barcode is readable with a standard barcode reader.	Test samples shall demonstrate readily readable barcodes	SDA test samples met the acceptance criteria for barcode testing to demonstrate that the SDA is substantially equivalent to the predicate device.

Test	Test Method Summary	Acceptance Criteria	Conclusions
Sterilization	ISO 11135 and AAMI TIR 28	Sterilization load shall pose an equal or lesser challenge to sterilize than existing sterile product loads.	SDA sterilization load met the acceptance criteria for sterilization to demonstrate that the SDA is substantially equivalent to the predicate device.
Shelf Life	ASTM F1980	Aged test samples must meet or exceed existing specifications	SDA test samples met the acceptance criteria for shelf life to demonstrate that the SDA is substantially equivalent to the predicate device.