December 6, 2017

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

Re: K172468
Trade/Device Name: 091 Long Sheath
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY, DTL, GCC
Dated: November 3, 2017
Received: November 6, 2017

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,

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)*
K172468

Device Name
091 Long Sheath

Indications for Use *(Describe)*
The 091 Long Sheath is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasulature.

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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Contact Information

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Date Prepared

December 4, 2017

Device Trade or Proprietary Name

091 Long Sheath

Device Common or Classification Name:

Catheter, Percutaneous, 21CFR870.1250, Class II
Hemostasis Valve, 21CFR870.4290, Class II
Vessel Dilator, 21 CFR 870.4200, Class I

Product Code:

DQY (Catheter)
DTL (Hemostasis Valve)
GCC (Vessel Dilator)

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

Name of Predicate Device	Name of Manufacturer	510(k) Number
AXS Infinity LS	Stryker	K152876

Device Description

The InNeuroCo, Inc. 091 Long Sheath is a variable stiffness catheter that has a catheter shaft reinforced with a stainless steel double coil. It has a radiopaque Platinum/Iridium marker band on the distal end. The distal 10 cm of the 091 Long Sheath Catheter has a hydrophilic coating. The catheter has a nominal outer diameter of 0.109 inches and a nominal inner diameter of 0.091 inches. It is available in three working lengths: 70 cm, 80 cm, and 90 cm. The 091 Long Sheath has a PTFE-lined lumen. The 091 Long Sheath is inserted at a vascular access point to provide 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 and a Vessel Dilator. The 091 Long Sheath is supplied sterile, non-pyrogenic, and intended for single use only.

Indications for Use

The 091 Long Sheath is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.

Comparison to Predicate Device

	Stryker AXS Infinity LS	**InNeuroCo 091 Long Sheath**
510(k) Number	K152876	K172468
Classification	21CFR870.1250, Class II	21CFR870.1250, Class II
Product Code	DQY	Same
Review Panel	Cardiovascular	Same
Indications For Use	The AXS Infinity LS is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.	The 091 Long Sheath is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.
Components Supplied	Sheath, Vessel Dilator, Hemostasis Valve	Same
Catheter Shaft Material	Polyether Block Amide, (PEBAX) and Chronoflex	Same
Inner Liner	PTFE	Same
Hub Material	Polycarbonate	Same
Strain Relief	Polyolefin	Same
Catheter Shaft Reinforcement	Stainless Steel Braid	Stainless Steel Double-Coil
Lubricious Coating	Harland Hydrophilic Coating	Same
Radiopaque Marker Band	Platinum/ Iridium	Same

	Stryker AXS Infinity LS	InNeuroCo 091 Long Sheath
Packaging	Tyvek/Nylon Pouch, polyethylene support tube, packaging card, SBS carton	Same
Sterilization	Ethylene Oxide	Same
Pyrogenicity	Nonpyrogenic	Same
Working Lengths	70, 80, 90 cm	Same
Internal Diameter	0.088 inches	0.091 inches
Outer Diameter	0.109 inches	Same
Vessel Dilator	Aid in sheath introduction during procedure	Same
Hemostasis Valve	Minimizes blood loss	Same
Luer Tapered Hub	Yes	Same

091 Long Sheath 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 than 0.5°C in any individual subject.	Test results for the InNeuroCo Super Distal Access (K161262) and the Zenith Catheter (K171672) were leveraged for the 091 Long Sheath as the materials and manufacturing	Yes

Test	Test Method Summary	Acceptance Criteria	Conclusions	Predicate Device Testing (Yes/Unknown)
			processes are equivalent. Test articles met the acceptance criteria for Material Mediated Pyrogen.	
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 InNeuroCo Super Distal Access (K161262) and the Zenith Catheter (K171672) were leveraged for the 091 Long Sheath as the materials and manufacturing processes are equivalent. Test articles met the acceptance criteria for Cytotoxicity MEM Elution.	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%.	Test results for the InNeuroCo Super Distal Access (K161262) and the Zenith Catheter (K171672) were leveraged for the 091 Long Sheath as the materials and manufacturing processes are equivalent. Test articles met the acceptance criteria for Hemolysis ASTM	Yes

Test	Test Method Summary	Acceptance Criteria	Conclusions	Predicate Device Testing (Yes/Unknown)
			Method, extract human blood.	
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%.	Test results for the InNeuroCo Super Distal Access (K161262) and the Zenith Catheter (K171672) were leveraged for the 091 Long Sheath as the materials and manufacturing processes are equivalent. Test articles met the acceptance criteria for Hemolysis, ASTM method, direct contact (human blood).	Yes
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 InNeuroCo Super Distal Access (K161262) and the Zenith Catheter (K171672) were leveraged for the 091 Long Sheath as the materials and manufacturing processes are equivalent. Test article met the acceptance criteria for Unactivated Partial Thromboplastin Time.	Yes

Test	Test Method Summary	Acceptance Criteria	Conclusions	Predicate Device Testing (Yes/Unknown)
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 InNeuroCo Super Distal Access (K161262) and the Zenith Catheter (K171672) were leveraged for the 091 Long Sheath as the materials and manufacturing processes are equivalent. Test article met the acceptance criteria for Complement Activation.	Yes
Biocompatibility-Dog Thrombogenicity	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 InNeuroCo Super Distal Access (K161262) and the Zenith Catheter (K171672) were leveraged for the 091 Long Sheath as the materials and manufacturing processes are equivalent. Test article met the acceptance criteria for Dog Thromboresistanc e.	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.	Test results for the InNeuroCo Super Distal Access (K161262) and the Zenith Catheter (K171672) were	Yes

Test	Test Method Summary	Acceptance Criteria	Conclusions	Predicate Device Testing (Yes/Unknown)
			leveraged for the 091 Long Sheath as the materials and manufacturing processes are equivalent. Test article met the acceptance criteria for Maximization Sensitization.	
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 InNeuroCo Super Distal Access (K161262) and the Zenith Catheter (K171672) were leveraged for the 091 Long Sheath as the materials and manufacturing processes are equivalent. Test article met the acceptance criteria for Intracutaneous Toxicity/Reactivity.	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.	Test results for the InNeuroCo Super Distal Access (K161262) and the Zenith Catheter (K171672) were leveraged for the 091 Long Sheath as the materials and manufacturing processes are equivalent. Test	Yes

Test	Test Method Summary	Acceptance Criteria	Conclusions	Predicate Device Testing (Yes/Unknown)
			article met the acceptance criteria for Acute Systemic Toxicity Test.	
Animal Testing-Angiographic Evaluation	Product evaluated within a porcine model for clinically significant injury.	No units tested can cause vessel injury.	Test article met the acceptance criteria for Animal Testing-Angiographic Evaluation.	Yes
Bench Testing - Chemical Compatibility	Catheter exposed to chemicals readily available in a clinical setting.	Chemicals have no negative effect on the catheter or accessories.	Test results for the InNeuroCo Super Distal Access (K161262) were leveraged for the 091 Long Sheath as the materials and manufacturing processes are equivalent. Test articles met the acceptance criteria for Chemical Compatibility	Yes
Bench Testing - Visual Inspection	Testing completed per ISO 10555-1	Catheter shall appear free from damage, including a rounded tip and smooth transition points.	091 Long Sheath test samples met the acceptance criteria for Visual Inspection.	Yes
Bench Testing - Dimensions	Testing completed per ISO 10555-1	Test samples should be within existing dimensional specifications.	091 Long Sheath test samples met the acceptance criterial for dimensions. Test results for the	Yes

Test	Test Method Summary	Acceptance Criteria	Conclusions	Predicate Device Testing (Yes/Unknown)
			InNeuroCo Super Distal Access (K161262) were leveraged for the Hemostasis Valve, which met the dimensional acceptance criteria.	
Bench Testing - Hub compatibility	Testing completed per ISO 594-1 and ISO 594-2	Hub shall meet existing Luer specifications.	Test results for the InNeuroCo Intermediate Catheter (K152202) were leveraged for the 091 Long Sheath and the Dilator as the materials and manufacturing processes are equivalent. The test results for the Super Distal Access (K161262) were leveraged for the 091 Long Sheath Hemostasis Valve. All tested samples met the acceptance criteria for Hub compatibility.	Yes
Bench Testing - Leak – Air	Testing completed per ISO 10555-1	Test samples should be within existing Air – Leak specifications.	091 Long Sheath test samples met the acceptance criteria for Leak – Air.	Yes

Test	Test Method Summary	Acceptance Criteria	Conclusions	Predicate Device Testing (Yes/Unknown)
Bench Testing - Leak – Liquid	Testing completed per ISO 10555-1	Test samples should be within existing Leak – Liquid specifications.	091 Long Sheath test samples met the acceptance criteria for Leak – Liquid.	Yes
Bench Testing - Particulates	Testing completed per USP 788	Test samples should be within existing Particulate specifications.	091 Long Sheath test samples met the acceptance criteria for Particulates.	Yes
Bench Testing - Simulated Use	LS underwent simulated use testing by a physician in a benchtop model	Test samples must meet predetermined user needs	091 Long Sheath test samples met the acceptance criteria for Simulated Use - Bench.	Yes
Bench Testing - Catheter Burst	Testing completed per ISO 10555-1	Test sample burst pressures must meet or exceed existing minimum burst pressure specification.	091 Long Sheath test samples met the acceptance criteria for Catheter Burst.	Yes
Bench Testing - Tensile	Testing completed per ISO 10555-1	Test sample ultimate tensile strength must meet or exceed existing tensile strength specifications.	091 Long Sheath test samples met the acceptance criteria.	Yes
Bench Testing - Corrosion	Testing completed per ISO 10555-1	Test samples shall exhibit no evidence of corrosion.	Test results for the InNeuroCo Intermediate Catheter (K152202) were leveraged for the 091 Long Sheath as the materials and manufacturing processes are	Yes

Test	Test Method Summary	Acceptance Criteria	Conclusions	Predicate Device Testing (Yes/Unknown)
			equivalent. All samples met the acceptance criteria.	
Bench Testing - Packaging – Dye Leak	Testing completed per ASTM F1929-12	Test sample shall not exhibit any visual leaks or channels	091 Long Sheath test samples met the acceptance criteria for Packaging – Dye Leak.	Yes
Bench Testing - Packaging – Peel	Testing completed per ASTM F88-09	Test sample tensile strength must meet or exceed existing tensile strength specifications.	091 Long Sheath test samples met the acceptance criteria for Packaging - Peel.	Yes
Bench Testing - Kink Resistance	Samples are subjected to different diameters until kink is observed.	Test sample kink resistance must meet or exceed existing Kink Resistance specifications.	091 Long Sheath test samples met the acceptance criteria for Kink Resistance.	Yes
Bench Testing - Torque	Conditioned samples are torqued to failure	Test sample torque results must meet or exceed existing torque specifications.	091 Long Sheath test samples met the acceptance criteria for Torque.	Yes
Bench Testing - PTFE Liner inspection	LS was challenged to demonstrate liner adherence.	Test sample liner adhesion must meet or exceed existing PTFE Liner inspection specifications.	091 Long Sheath test samples met the acceptance criteria for PTFE Liner inspection.	Yes
Bench Testing - Hydrophilic Coating Integrity	Conditioned samples were repeatedly exposed to friction to	Test sample results must meet or exceed existing Hydrophilic Coating	091 Long Sheath test samples met the acceptance criteria for	Yes

Test	Test Method Summary	Acceptance Criteria	Conclusions	Predicate Device Testing (Yes/Unknown)
	demonstrate that the hydrophilic coating is not affected.	Integrity specifications.	Hydrophilic Coating Integrity.	
Bench Testing - Labeling Legibility	Label is legible after printing.	Test samples shall demonstrate text legibility.	091 Long Sheath test samples met the acceptance criteria for labeling legibility.	Yes
Bench Testing - Barcode	Barcode is readable with a standard barcode reader.	Test samples shall demonstrate readily readable barcodes	091 Long Sheath test samples met the acceptance criteria for barcode testing.	Yes
Sterilization	ISO 11135 and AAMI TIR 28	Sterilization load shall pose an equal or lesser challenge to sterilize than existing sterile product loads.	091 Long Sheath sterilization load met the acceptance criteria for sterilization.	Yes
Bacterial Endotoxin	AAMIST72	Test samples must meet the bacterial endotoxin acceptance criteria	The 091 Long Sheath samples met the acceptance criteria for bacterial endotoxins.	Yes
Shelf Life	ASTM F1980	Aged test samples must meet or exceed existing specifications	091 Long Sheath test samples met the acceptance criteria for shelf life.	Yes

Summary of Non-Clinical Data

The conclusions drawn from the physical, mechanical, and performance testing of the subject 091 Long Sheath along with the data leveraged from other commercially available products demonstrate that the product is Substantially Equivalent to the legally marketed predicate device.