DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 8, 2016

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

Re: K152876
Trade/Device Name: Long Sheath
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: December 3, 2015
Received: December 7, 2015

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,

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)*
K152876

Device Name
Long Sheath

Indications for Use *(Describe)*
The 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

Submitter's Name and Address

TNI Manufacturing, 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 25, 2015

Device Trade or Proprietary Name

Long Sheath or LS

Device Common or Classification Name:

Catheter, Percutaneous, 21CFR870.1250, Class II

Product Code:

DQY

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

Name of Predicate Device	Name of Manufacturer	510(k) Number
NEURON MAX SYSTEM	Penumbra, Inc. Alameda, California	K111380

Device Description

The Long Sheath or LS is a variable stiffness catheter and has a catheter shaft reinforced with a stainless steel braid and has a radiopaque Platinum/Iridium marker band on the distal end. The catheter has a nominal outer diameter of 0.109 inches. It is available with a nominal inner diameter of 0.088 inches. They are available in three working lengths: 70 cm, 80 cm, and 90 cm. The Long Sheath has a PTFE-lined lumen, which is braid-reinforced, flexible, and has a hydrophilic coating. The LS are inserted through a guide catheter or vascular sheath, provide access to the target site and once in place, provide a reinforcing conduit for other intravascular devices. Accessories included with the device are a Tuohy-Borst hemostasis valve with an extension luer and a dilator. The LS is supplied sterile, non-pyrogenic, and intended for single use only.

Indications for Use

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

Comparison to Predicate Device

	Predicate Device **Penumbra NEURON MAX SYSTEM**	**TNI Manufacturing, Inc. Long Sheath**
510(k) Number	K111380	K152876
Classification	21CFR870.1250, Class II	21CFR870.1250, Class II
Product Code	DQY	DQY

Review Panel	Cardiovascular	Cardiovascular
Indication For Use	The Neuron™ MAX System is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.	The Long Sheath is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.
Components Supplied	Sheath, Vessel Dilator, Hemostasis Valve,	Sheath, Vessel Dilator, Hemostasis Valve
Catheter Shaft Material	Nylon, Polyurethane	Polyether Block Amide, (PEBAX)
Inner Liner	PTFE	PTFE
Hub Material	Polycarbonate	Polycarbonate
Strain Relief	Polyolefin	Polyolefin
Catheter Shaft Reinforcement	Stainless Steel Braid	Stainless Steel Braid
Lubricious Coating	Hydrophilic Coating	Hydrophilic Coating
Radiopaque Marker Band	Platinum/ Iridium	Platinum/ Iridium
Packaging	Tyvek Pouch, polyethylene support tube, packaging card, SBS carton	Tyvek/Nylon Pouch, polyethylene support tube, packaging card, SBS carton
Sterilization	Ethylene Oxide	Ethylene Oxide
Pyrogenicity	Nonpyrogenic	Nonpyrogenic
Working Lengths	70, 80, 90, and 100 cm	70, 80, 90 cm
Internal Diameter	0.088 inches	0.088 inches
Outer Diameter	0.108 inches	0.109 inches
Shelf Life	3 years	3 years

Vessel Dilator	Aid in sheath introduction during procedure	Aid in sheath 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 Long Sheath and 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 Long Sheath to be biocompatible and non-pyrogenic.

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

Long Sheath Performance Testing

Test	Test Method Summary	Results
Biocompatibility	Testing completed per ISO 10993-1	All units tested meet the acceptance criteria. All samples met the acceptance criteria
Radiographic Detectability	Testing completed per ISO 10555-1	All units tested must meet the acceptance criteria. All samples met the acceptance criteria
Visual Inspection	Testing completed per ISO 10555-1	All units tested must meet the acceptance criteria. All samples met the acceptance criteria
Working Length	Testing completed per ISO 10555-1	All units tested must meet the acceptance criteria. All samples met the acceptance criteria
Hub compatibility	Testing completed per ISO 594-1 and ISO 594-2	All units tested must meet the acceptance criteria. All samples met the acceptance criteria

Test	Test Method Summary	Results
Outside diameter	Testing completed per ISO 10555-1	All units tested must meet the acceptance criteria. All samples met the acceptance criteria
Leak – Air	Testing completed per ISO 10555-1	All units tested must meet the acceptance criteria. All samples met the acceptance criteria
Leak – Liquid	Testing completed per ISO 10555-1	All units tested must meet the acceptance criteria. All samples met the acceptance criteria
Particulates	Testing completed per USP 788	All units tested must meet the acceptance criteria. All samples met the acceptance criteria
Catheter Burst	Testing completed per ISO 10555-1	All units tested must meet the acceptance criteria. All samples met the acceptance criteria
Tensile	Testing completed per ISO 10555-1	All units tested must meet the acceptance criteria. All samples met the acceptance criteria
Corrosion	Testing completed per ISO 10555-1	All units tested must meet the acceptance criteria. All samples met the acceptance criteria
Packaging – Dye Leak	Testing completed per ASTM F1929-12	All units tested must meet the acceptance criteria. All samples met the acceptance criteria
Packaging – Peel	Testing completed per ASTM F88-09	All units tested must meet the acceptance criteria. All samples met the acceptance criteria