



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 14, 2015

TNI Manufacturing, Inc.
% Mr. Mark Job
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, Minnesota 55313

Re: K152202

Trade/Device Name: Intermediate Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY, DYB, DTL
Dated: November 19, 2015
Received: November 23, 2015

Dear Mr. Job:

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" (21CFR 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. Peña 

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

Enclosure

Indications for Use

510(k) Number (if known)

K152202

Device Name

Intermediate Catheter

Indications for Use (Describe)

The Intermediate 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.

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
PRASStaff@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

TNI Manufacturing, Inc.
4635 NW 103rd Avenue
Sunrise, Florida 33351
Telephone: 1-954-742-5988
Facsimile: 1-954-742-5989

Contact Information

Daniel Sablyak
President
4635 NW 103rd Avenue
Sunrise, Florida 33351
Telephone: 1-954-742-5988
Facsimile: 1-954-742-5989
E-Mail: Dan@tnimfg.com

Date Prepared

November 16, 2015

Device Trade or Proprietary Name

Intermediate Catheter
Hemostasis Valve
Split Sheath Introducer

Device Common or Classification Name:

Catheter, Percutaneous, 21CFR870.1250, Class II
Hemostasis Valve, 21CFR870.4290, Class II
Catheter Introducer, 21CFR870.1340, Class II

Product Code:

DQY (Catheter)

DTL (Hemostasis Valve)

DYB (Catheter Dilator)

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

Name of Predicate Device	Name of Manufacturer	510(k) Number
5MAX™ DDC Distal Delivery Catheters	Penumbra, Inc. Alameda, California	K122772

Device Description

The Intermediate Catheter is a variable stiffness catheter and has a catheter shaft reinforced with a stainless steel braid, a stainless steel coil, a Nitinol coil, and has a radiopaque Platinum/Iridium marker band on the distal end. The catheter has a nominal distal outer diameter of 0.072" and a nominal proximal outer diameter of 0.078". It is available with a nominal inner diameter of 0.060". They are available in three working lengths, 105 cm, 115 cm, and 125 cm. The Intermediate Catheters have a PTFE-lined lumen, which is braid and coil reinforced, flexible, and has a hydrophilic coating. The Intermediate Catheters are inserted through a guide catheter or vascular sheath, 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 split introducer sheath. The Intermediate Catheter is supplied sterile, non-pyrogenic, and intended for single use only.

Indications For Use

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

Comparison to Predicate Device

	Predicate Device Penumbra 5MAX™ DDC	Intermediate Catheter
510(k) Number	K122772	K152202
Classification	21CFR870.1250, Class II	Same
Product Code	DQY	Same
Indication For Use	The DDC Catheters are 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.
Inner Lumen	PTFE	PTFE
Catheter Shaft Material	Nylon, PTFE, polyurethane, hydrophilic coating	Nylon, PTFE, polyimide, polyether block amide, PET, polycarbonate/urethane hydrophilic coating
Hub Material	Polycarbonate	Same
Catheter Shaft Reinforcement	Stainless Steel/Nitinol	Same
Marker Band	Platinum/Iridium	Same
Packaging	Tyvek Pouch, polyethylene support hoop, packaging card, SBS Carton	Same
Sterilization	Ethylene Oxide	Same
Pyrogenicity	Nonpyrogenic	Same
Inside Diameter (ID)	0.062”	Same
Outside Diameter (OD)	6 Fr	Same
Working Lengths (cm)	115 and 125 cm	105, 115, and 125 cm

	Predicate Device Penumbra 5MAX™ DDC	Intermediate Catheter
Compatible Guidewire	0.038”	Same

Summary of Non Clinical Data

Biocompatibility tests conducted with the Intermediate Catheters 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 Intermediate Catheters to be biocompatible and non-pyrogenic.

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

Intermediate Catheter Performance Testing

Test	Test Method Summary	Results
Biocompatibility	Testing completed per ISO 10993-1	All units tested must meet the acceptance criteria. All samples met the acceptance criteria.
Sterilization Validation	Testing completed per ISO 11135	All units tested must 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.

Test	Test Method Summary	Results
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.
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.