January 13, 2020

Route 92 Medical Inc.
Kathy Tansey
Senior Director of Regulatory Affairs and Quality Assurance
1700 S. El Camino Real, Suite 206
San Mateo, California 94402

Re: K191717
Trade/Device Name: Base Camp™ Sheath System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: December 12, 2019
Received: December 13, 2019

Dear Kathy Tansey:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Xiaolin Zheng, Ph.D., M.S.
Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191717

Device Name
Base Camp Sheath System

Indications for Use *(Describe)*
The Route 92 Medical Sheath System 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

Sponsor:	Route 92 Medical 1700 S. El Camino Real, Suite 206 San Mateo, CA 94022 Phone: 650-581-1179 Fax: 650-343-5827
Contact:	Kathy Tansey
Date Prepared:	June 25, 2019
Device Trade Name:	Base Camp™ Sheath System
Common Name:	Percutaneous Catheter
Classification Name:	Percutaneous Catheter (Product Code DQY, 21 CFR 870.1250)
Legally Marketed Predicate Device:	TNI Manufacturing, Inc. Long Sheath (K152876)

Device Description

The Route 92 Medical Sheath System is comprised of a Sheath, a Dilator, a Navigating Catheter, and an RHV (rotating hemostasis valve). The Sheath is a single-lumen, variable stiffness catheter with a radiopaque marker on the distal end. The inner lumen of the catheter is compatible with 8F or smaller catheters. The Dilator may be placed within the Sheath to facilitate percutaneous introduction of the Sheath into a femoral artery. The Dilator has a radiopaque marker at the distal tip. The Navigating Catheter is a single-lumen, variable stiffness catheter with a radiopaque marker at the distal tip. The Navigating Catheter is compatible with the Sheath and has a shaped distal end to facilitate placement. All of the catheters are coated with hydrophilic coating.

Indications for Use

The Route 92 Medical Sheath System is indicated for the introduction of interventional devices into the peripheral and neuro vasculature.

Comparison to Predicate Device

The intended use, method of action, design, and materials of the Route 92 Medical Sheath System are substantially equivalent to the TNI Manufacturing, Inc. Long Sheath (K152876) predicate device as shown in the following table.

Attribute	TNI Manufacturing, Inc. Long Sheath, K152876 (Predicate Device)	Route 92 Medical Sheath System (Subject Device)
Indications for Use	The Long Sheath is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.	The Route 92 Medical Sheath System is indicated for the introduction of interventional

Attribute	TNI Manufacturing, Inc. Long Sheath, K152876 (Predicate Device)	Route 92 Medical Sheath System (Subject Device)
		devices into the peripheral and neuro vasculature.
Device Description	A single-lumen flexible, variable stiffness catheter with a hydrophilically-coated, shaft and a radiopaque marker band on the distal end.	Same as predicate
User	Physicians trained in endovascular techniques	Same as predicate
Anatomical Sites	Peripheral, coronary and neuro vasculature	Peripheral and neuro vasculature
Method of Action	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. Includes component(s) to facilitate percutaneous introduction and intravascular tracking of the device.	Same as predicate device
Lubricious Coating	Hydrophilic coating	Same as predicate device
Packaging	Tyvek pouch, packaging card and SBS carton	Same as predicate device
Sterilization	Ethylene oxide	Same as predicate device
Materials	Polymers and metals commonly used in the manufacture of medical devices	Same as predicate device
Dimensions		
Working Length(s)	70, 80, 90 cm	90 cm
Inner Diameter (min)	0.088”	0.106”
Outer Diameter	0.109”	0.122”

Non-Clinical Testing

Biocompatibility Testing

The Route 92 Medical Sheath System is constructed using materials that are commonly used in the medical device industry. All patient contacting components have been evaluated for biocompatibility in accordance with ISO 10993-1 Biological Evaluation of Medical Devices Part 1: Evaluation and Testing. The Route 92 Medical Sheath System is classified per ISO 10993-1 as externally communicating with limited circulating blood contact (<24 hours). A summary of the biocompatibility testing is provided below.

A reference device (Flexor Tuohy-Borst Side-Arm Introducer, K142819) was chosen as the control device for SC5b-9 Complement Activation Assay and in vivo Thromboresistance evaluation.

Test	Results	Conclusions
Cytotoxicity – ISO MEM Elution	No cytotoxicity or cell lysis was noted in any of the test wells (reactivity grade = 0). The test article extract met the requirements of the test as the grade was less than 2.	The test article is non-cytotoxic.
Sensitization – ISO Guinea Pig Maximization Sensitization Test (Sodium Chloride USP Solution and Sesame Oil)	The test article extracts showed no evidence of causing delayed dermal contact sensitization in the guinea pig (no findings in clinical observations and grade = 0 for dermal reactions). The test article was not considered a sensitizer in the test.	Test article did not elicit a sensitization response.
Irritation – ISO Intracutaneous Reactivity (Sodium Chloride USP Solution and Sesame Oil)	The test article met the requirements of the test since the difference between each test article extract overall mean score and corresponding control extract overall mean score was 0.0 and 0.0 for sodium chloride and sesame oil test article extracts, respectively.	Requirements of the ISO intracutaneous reactivity test have been met for the test article.
Acute Systemic Toxicity – ISO Acute Systemic Injection (Sodium Chloride USP Solution and Sesame Oil)	There was no mortality or evidence of systemic toxicity from the injected extracts. All animals treated had were clinically normal throughout the study as compared to control mice.	Requirements of the ISO acute systemic injection test have been met for the test article.
Material Mediated Pyrogenicity	No single animal showed a temperature rise of 0.5ºC or more above its baseline temperature. The total rise of the rabbits' temperature during 3 hours was 0.2 ºC. The total rise of rabbit temperatures during the 3-hour observation period was within acceptable USP requirements. The test article met the requirements for the absence of pyrogens.	The test article met the requirements for the absence of pyrogens.
Hemocompatibility – Partial Thromboplastin Time	The test articles met the requirements of the test and were not different statistically from the negative control and the negative reference material.	The test article is considered to be a non-activator of the intrinsic coagulation pathway.
Hemocompatibility – ASTM Hemolysis	Blank corrected hemolytic index above the negative control: Direct Method: 0.0% Extract Method: 0.4%	The test article is considered non-hemolytic.
Hemocompatibility – Complement Activation Assay	When compared to a legally US-marketed device, the complement activation noted in the test article would not be expected to result in adverse effects in vivo.	The test article is considered to be a low potential activator of the complement system.

Test	Results	Conclusions
Hemocompatibility – *in-vivo* Thromboresistance	When compared to a legally US-marketed device, the test articles and control articles were comparable. No to minimal thrombus formation was noted with both test and control articles.	The test article is comparable to a legally US-marketed device.

Performance Testing

The successful completion of the performance testing listed in the following table demonstrates that the Route 92 Medical Sheath System is suitable for its intended use.

Test	Test Method	Results
Dimensional Verification	Device dimensions were measured to confirm conformance to the specifications	**PASS** All samples met the pre-determined acceptance criteria
Luer Integrity	Tested per ISO 80369-7:2016	**PASS** All samples met the pre-determined acceptance criteria
Tensile Strength	The tensile strength of the catheter sections and bonds was tested	**PASS** All samples met the pre-determined acceptance criteria
Kink Resistance	Test specimen segments were formed into a defined bend diameter to evaluate kink resistance	**PASS** All samples met the pre-determined acceptance criteria
Torsion Resistance	The test specimens were rotated to evaluate integrity after rotation	**PASS** All samples met the pre-determined acceptance criteria
Tip Flexibility	Test specimens were tested for tip flexibility	**PASS** All samples met the pre-determined acceptance criteria
Air Leakage	Tested per ISO 10555-1:2013 Annex D.	**PASS** All samples met the pre-determined acceptance criteria
Liquid Leakage	Tested per ISO 10555-1:2013 Annex C.	**PASS** All samples met the pre-determined acceptance criteria

Test	Test Method	Results
Hydrophilic Coating Integrity	The integrity of the hydrophilic coating was evaluated after multiple insertion and withdrawal cycles.	**PASS** All samples met the pre-determined acceptance criteria
Particulate Recovery	After multiple insertion and withdrawal cycles, the effluent water flushed from the model was tested per USP <788>.	**PASS** All samples met the pre-determined acceptance criteria
Simulated Use Testing	Deliverability and compatibility with accessory devices was evaluated in a vascular model	**PASS** All samples met the pre-determined acceptance criteria
Packaging Integrity	ISO 11607-1 Part 1 ISO 11607-2 Part 2	**PASS** All samples met the pre-determined acceptance criteria
Radiopacity	Radiopacity of the device was evaluated in an animal model under fluoroscopy	**PASS** All samples met the pre-determined acceptance criteria

Substantial Equivalence

The Route 92 Medical Sheath System is substantially equivalent to the predicate TNI Manufacturing, Inc. Long Sheath (K152876) in intended use, design, principles of operation, technology and performance. The successful completion of biocompatibility testing and performance testing demonstrates that the Route 92 Medical Sheath System is safe and effective for its intended use and substantially equivalent to the predicate device.