September 27, 2023

Inneuroco Inc.
Garry Koroshec
Staff Design Quality Engineer / Regulatory Affairs
19700 Stirling Road, Suite 1
Pembroke Pines, Florida 33332

Re: K232260
Trade/Device Name: Thinline Sheath Introducer
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: July 28, 2023
Received: July 31, 2023

Dear Garry Koroshec:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Finn E. Donaldson -S

Digitally signed by Finn E. Donaldson -S
Date: 2023.09.27 14:15:45 -04'00'

For
Misti Malone
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232260

Device Name
Thinline Sheath Introducer

Indications for Use *(Describe)*
The Thinline Sheath Introducer is intended to provide access and facilitate the percutaneous introduction of various devices into veins and/or arteries while maintaining hemostasis for a variety of diagnostic and therapeutic procedures.

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

Date Summary Prepared	September 27, 2023
Submitter	InNeuroCo Inc. 19700 Stirling Road, Suite 1 Pembroke Pines, FL 33332
Primary Submission Contact	Garry Koroshec Staff Design Quality Engineer / Regulatory Affairs InNeuroCo Inc. 19700 Stirling Road, Suite 1 Pembroke Pines, FL 33332 Telephone: 1-954-254-5003 Facsimile: 1-954-742-5989 E-Mail: garry@inneuroco.com
Secondary Submission Contacts	Marianne Grunwaldt Senior Director of Regulatory Affairs and Quality Assurance InNeuroCo Inc. 19700 Stirling Road, Suite 1 Pembroke Pines, FL 33332 Telephone: 1-954-703-5271 Facsimile: 1-954-742-5989 E-Mail: marianne@inneuroco.com Ming Cheng Chew Regulatory Consultant RQM+ 8401 73rd Avenue North, Suite 63 Brooklyn Park, MN 55428 Telephone: 763-232-3701 E-Mail: mchew@rqmplus.com
Trade name	Thinline Sheath Introducer
Regulation Number	21 CFR 870.1340
Device Common or Classification Name	Catheter Introducer
Product Class	Class II
Product Panel	Cardiovascular
Product Code	DYB
Predicate Device	Merit Prelude Ideal 9F Hydrophilic Sheath Introducer #K212152
Reference Device	Zenith (065 and 074) #K171672

6.1 Device Description

The Thinline Introducer Sheath is a single-lumen, coil-reinforced catheter. The Thinline Introducer Sheath is available in 11cm and 23cm lengths (French size 9F) and is designed to accept 0.038 inch diameter guide wires. A radiopaque outer layer is included for angiographic visualization. A valved hub with integrated suture ring is attached to the proximal end with extension tubing and a three way stop cock which allows attachments for flushing and aspiration. This catheter is designed for use in providing access and facilitating the percutaneous introduction of various devices into veins and/or arteries while maintaining hemostasis for a variety of diagnostic and therapeutic procedures. The dimensions for the Thinline Introducer Sheath are indicated on the product label. A dilator and guidewire accessory are included within the packaging. It is supplied sterile, non-pyrogenic, and is intended for single use only.

6.2 Indications for Use

The Thinline Sheath Introducer is intended to provide access and facilitate the percutaneous introduction of various devices into veins and/or arteries while maintaining hemostasis for a variety of diagnostic and therapeutic procedures.

6.3 Technological Characteristics and Basis for Substantial Equivalence

Table 6.1 Technological Comparison between the Thinline Introducer Sheath and Prelude Ideal 9F Hydrophilic Sheath Introducer (K212152)

Parameter	Predicate Device Prelude Ideal 9F Hydrophilic Sheath Introducer (K212152)	Subject Device Thinline Introducer Sheath (K232260)
Indications for Use	The 9F Prelude Ideal Hydrophilic Sheath Introducer is intended to provide access and facilitate the percutaneous introduction of various devices into veins and/or arteries while maintaining hemostasis for a variety of diagnostic and therapeutic procedures.	The Thinline Sheath Introducer is intended to provide access and facilitate the percutaneous introduction of various devices into veins and/or arteries while maintaining hemostasis for a variety of diagnostic and therapeutic procedures.
Anatomical Location	Cardiovascular	Cardiovascular
Product Code	DYB	DYB
Classification	Class II	Class II
Regulation Number	870.1340	870.1340
Coating	Yes	Yes
Internal construction	Single Lumen	Single Lumen
Working Length	11 cm, 23 cm	11 cm, 23 cm
Max Outer Diameter	0.138 inches	0.142 inches
Shaft Inner diameter	0.126 inches	0.126 inches
Accessories supplied	Dilator Guidewire Metal Access Needle Guide Wire Insertion Device	Dilator Guidewire
Sterilization	Ethylene Oxide	Ethylene Oxide
Number of Uses	Single Use	Single Use

6.4 Performance Data

Design verification and validation were performed to ensure that the Thinline Introducer Sheath meets its performance specifications and demonstrates substantial equivalence to the predicate device. A list of the performance testing conducted is presented below in Table 6.2. Some of the tests were also conducted on the predicate device to help establish substantial equivalence. All pre-determined acceptance criteria were met.

In some cases, verification test data were leveraged from data that had been generated from testing done on previously cleared devices.

Table 6.2 – Performance Bench Tests Performed on the Thinline Introducer Sheath

Test performed	Test Summary	Results
Design Verification Testing		
Tensile Strength	Testing was completed per ISO 10555-1, Section 4.6 and Annex B.	**Pass**
PTFE delamination	PTFE liner was visually inspected to ensure that delamination of the liner was not present.	**Pass**
Torque Strength	The device must withstand one turn of the hub	**Pass**
Catheter Burst	Testing was completed per ISO10555-1, Section 4.10 and Annex F.	**Pass**
Visual Inspection	Samples were visually inspected under 2.5X magnification to ensure acceptance criteria were met.	**Pass**
Particulates	Testing was completed per USP <788>. Testing was also performed in comparison to the predicate.	**Pass**
Liquid Leak Test (sheath and hemostasis valve)	Testing was conducted per ISO 10555-1, Section 4.7 and Annex C.	**Pass**
Air Leak Test	Testing was conducted per ISO 10555-1 section 4.7.2 and Annex D.	**Pass**
Dimensional Verification	The catheter and introducer must meet specifications	**Pass**
Coating Length	The sheath length with hydrophilic coating must meet specifications	**Pass**
Chemical Compatibility	The device shall withstand exposure to saline, dextrose, heparin, and contrast	**Pass**
Tip Flexibility/Stiffness	Units will be held at 5 mm, 10 mm, and 20 mm from the distal tip, and a tensile test stand will be used to record the force required to displace the tip by 1 mm. Testing conducted per FDA Guidance Document #1600, Coronary, Peripheral, and Neurovascular Guidewires – Performance Tests and Recommended Labeling.	**Pass**
Hub Compatibility	Catheter luers shall be tested per ISO 594-1:1986 and ISO 594-2:1998	**Pass**
Kink Resistance	After conditioning, two points on each test sample were wrapped around progressively smaller diameter pegs and/or mandrels until a kink was observed.	**Pass**
Packaging – Pouch Leak Test	Testing was conducted per ASTM F-1929.	**Pass**
Packaging – Pouch Peel Test	Testing was conducted per ASTM F88/F88M.	**Pass**
Packaging – Visual Inspection	Packaging was visually inspected to determine if any perforations, nicks, cuts, or punctures on the pouch were present. All pouch seals were also visually inspected to verify that seals were not damaged or peeled, and that all seals were intact.	**Pass**
Label Legibility	Labeling will be inspected visually to ensure text remains legible after transportation and environmental conditioning.	**Pass**
Packaging – Seal Width	The seals will meet the specified width	**Pass**
Design Validation Testing		
In-vitro Simulated Use Study – Benchtop	The Thinline Sheath Introducer was prepared per the IFU. A simulated interventional procedure was performed by physicians in order to verify the product's performance.	**Pass**

Test performed	Test Summary	Results
In-vitro Simulated Use Study – Useability	Participating physicians were asked to rate various aspects of the Thinline Sheath Introducer including performance and IFU	**Pass**

6.5 Biocompatibility testing

Biocompatibility of the Thinline Introducer Sheath was leveraged from the reference device (K171672) based on the similarities in design, materials, suppliers, and processing. The following biocompatibility endpoints were leveraged to support the substantial equivalence of the subject device:

Table 6.3 Summary of Biocompatibility Testing Leveraged from the Reference Device (K171672)

Biological Effect	Test
Cytotoxicity	MEM elution, 48 hr. inc., triplicate L929, 24 hr. ext. (nonimplant)
Sensitization	Magnusson-Kligman Method, 2 extracts
Irritation	Intracutaneous Toxicity (ISO), 2 extracts
Material mediated pyrogenicity	Material Mediated Pyrogen
Acute Systemic Toxicity	Systemic Injection (ISO), 2 extracts
Hemocompatibility	Hemolysis, ASTM Method, indirect (human blood)
	Hemolysis, ASTM Method, direct contact (human blood)
	Complement Activation, SC5b-9
	Dog Thrombogenicity

6.6 Sterilization Validation

A confirmatory sterilization study was conducted to verify that the subject device can be adopted into the previously validated ethylene oxide sterilization cycle. The device passed all sterility, EO residual, LAL, and bioburden testing.

6.7 Conclusion

Review of the verification and validation test data as well as comparison of the device classification, indications for use, operating principle, technological characteristics, sterility, and biocompatibility, demonstrate that the subject device, the Thinline Introducer Sheath, is substantially equivalent to the predicate Merit Prelude Ideal 9F Hydrophilic Sheath Introducer #K212152.