May 23, 2025

Piraeus Medical
Kristin M. Mortenson
VP of Quality and Regulatory
7351 Kirkwood Lane N, Suite 116
Maple Grove, Minnesota 55369

Re: K251044
Trade/Device Name: 93 NeuFlex Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP, DQY
Dated: April 24, 2025
Received: April 24, 2025

Dear Kristin Mortenson:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Naira Muradyan -S

Naira Muradyan, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional, and
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Office of Product Evaluation and Quality
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251044

Device Name
93 NeuFlex Catheter

Indications for Use *(Describe)*
The 93 NeuFlex Catheter is indicated for the introduction of interventional devices into the peripheral, coronary, 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.

510(k) Summary, K251044

A. Submitter Information

Submitter's Name:	Piraeus Medical
Address:	7351 Kirkwood Lane N, Suite 116 Maple Grove, MN 55369
Contact Person:	Jared Hutar
Telephone:	507-782-0184
Email:	quality@piraeusmedical.com
Date of Preparation:	May 20th, 2025

B. Correspondent Information

Contact Name:	Kristin Mortenson
Telephone:	507-782-0184
Email:	quality@piraeusmedical.com

C. Subject Device

Proprietary Name:	93 NeuFlex™ Catheter
Common/Usual Name:	Guide Catheter
Classification Name:	Catheter, Percutaneous, Neurovasculature
Product Codes:	QJP, DQY
Regulation:	21 CFR 870.1250

D. Predicate Device

Proprietary Name:	87 NeuGlide™ Catheter
Common/Usual Name:	Guide Catheter
Classification Name:	Catheter, Percutaneous, Neurovasculature
Product Codes:	QJP, DQY
Regulation:	21 CFR. 870.1250
Manufacturer:	Piraeus Medical
510(k) #'s:	K240971

E. Device Description

The Piraeus Medical 93 NeuFlex™ Catheter is a single lumen guide catheter that provides access to peripheral, coronary and neuro vasculature. The catheter is comprised of a hollow cylindrical tube bonded at the proximal end to a standard luer fitting. The wall of the tube is constructed using a combination of metal coils/braids and medical grade polymers. The catheter features a hydrophilic coating to enhance tracking through tortuous vasculature and facilitate the introduction of interventional devices to the peripheral, coronary and neuro vasculature. The 93 NeuFlex™ guide catheter is compatible with 0.035" or smaller guidewires. The distal soft tip facilitates tracking past vessel branches. A radiopaque marker provides visual confirmation of the distal tip location under fluoroscopy. The 93 NeuFlex™ Catheter has an inner diameter of 0.093" (compatible with 6F outer diameter catheters), and a maximum outer diameter of 0.110". The catheter is offered in working lengths of 110 cm and 100 cm. The 93 NeuFlex™ guide catheter is packaged with a loading tool to aid in insertion of the catheter into a short sheath.

Accessory devices required, but not supplied include:

- Guidewires
- Support/diagnostic catheters
- Introducer sheaths
- Rotating hemostasis valves (RHVs)

F. Indications for Use

The 93 NeuFlex™ Catheter is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.

G. Principles of Operation

The 93 NeuFlex™ Catheter may be used with support catheters to assist in accessing the target vasculature. Use of the 93 NeuFlex™ Catheter relies on standard percutaneous interventional techniques, including access site preparation, introducing the catheter portion of the device, advancing the catheter under fluoroscopy, withdrawing the catheter, and closing the access site.
Predicate Comparison:

H. Comparison with the Predicate

The predicate device is the 87 NeuGlide™ Catheter cleared under K240971. The predicate and subject devices share the same intended use and basic technological characteristics as shown in Table 1.

Table 1: Comparison of Predicate and Subject Devices

Device Attribute	Predicate Device (K240971)	Subject Device (K251044)
FDA Product Classification	Class II, QJP and DQY, 21 CFR 870.1250	Same
Device Name	87 NeuGlide™ Catheter	93 NeuFlex™ Catheter
Indications for Use	The 87 NeuGlide™ Catheter is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.	The 93 NeuFlex™ Catheter is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.
Condition Supplied	Sterile and Single Use	Same
Sterilization Method	Ethylene Oxide (EO), sterility assurance level (SAL) 10^{-6}	Same
Inner Diameter (Distal)	0.087”	0.093”
Outer Diameter (Distal)	0.100”	0.110”
Inner Diameter (Proximal)	0.087”	0.093”
Outer Diameter (Proximal)	0.100”	0.110”
Effective Lengths	100 cm and 110 cm	Same
Tip Design	Straight atraumatic tip	Same
Coating	Hydrophilic coating	Same
Materials	Commonly used medical grade plastics & metals with hydrophilic coating.	Same
Packaged Accessories	Loading Tool	Same
Packaging Configuration	The catheter is placed in a protective polyethylene tube, mounted with accessory loading tool onto a polyethylene packaging card, placed into a pouch, sealed and labeled. The sealed pouch and IFU are placed in a labeled shelf carton box.	Same

I. Performance Testing Supporting Substantial Equivalence

A summary of the supportive no-clinical testing is presented in Table 2. These tests were performed per company approved protocols, test methods, and performance standards.

Table 2: Tests and Performance Specifications

Test	Test Method Summary [standard and/or guidance]	Results
Visual Inspection	The catheter was examined for surface defects or extraneous matter. The distal tip was inspected to confirm the presence of smooth, tapered or rounded edges.	Pass
Dimensional Verification	The catheter outer diameter, inner diameter, usable length, and coating length were measured.	Pass
Delivery, Compatibility, and Retraction (Trackability)	The catheter shall be able to be prepped, inserted, tracked, and retracted and removed per the Instructions for Use within a simulated use model without incurring any damage to the catheter. [ISO 10555-1, FDA guidance PTA and Specialty Catheters]	Pass
Flexibility and Kink Resistance	There shall be no kinking of shaft (permanent deformation) after simulated use. [FDA guidance PTA and Specialty Catheters]	Pass
Compatibility with Other Devices (External)	The catheter is compatible with 8F introducer (short) sheath. [ISO 10555-1, FDA guidance PTA and Specialty Catheters]	Pass
Guidewire Compatibility	The catheter shall be able to be delivered over the maximum size guidewire indicated in the product labeling. [ISO 10555-1, FDA guidance PTA and Specialty Catheters]	Pass
Interventional Device Compatibility (Internal)	The catheter shall be able to accommodate other interventional devices (e.g., support catheter, diagnostic catheter) up to the maximum size indicated in the product labeling. [ISO 10555-1, FDA guidance PTA and Specialty Catheters]	Pass
Accessory Compatibility	Devices shall be compatible with accessories such as RHVs and the accessory loading tool.	Pass
Catheter Bond Strength	The catheter shall have sufficient tensile bond strength in comparison to measured retrieval forces to remain intact throughout a procedure. [ISO 10555-1, FDA guidance PTA and Specialty Catheters]	Pass
Freedom from Leakage – Positive Pressure	No liquid leakage from the hub or catheter shaft at 317 kPa (46 psi) for 30 seconds. [ISO 10555-1]	Pass
Freedom from Leakage – Negative Pressure	No air leakage into a 20cc syringe when vacuum pulled for 15 seconds. [ISO 10555-1]	Pass
Kink Resistance	There shall be no kinking of the catheter shaft (permanent deformation) after wrapping around anatomically relevant bend radii. [FDA guidance PTA and Specialty Catheters]	Pass
Pushability	The proximal shaft of the catheter shall have sufficient stiffness that the user can easily push the catheter to the target anatomy without buckling. [ISO 10555-1, FDA guidance PTA and Specialty Catheters]	Pass
Access Force	Catheter shall not require excessive force to navigate and track to the target anatomy. [ISO 10555-1, FDA guidance PTA and Specialty Catheters]	Pass
Static Burst	The distal tip of the catheter was blocked, and fluid was	Pass

Test	Test Method Summary [standard and/or guidance]	Results
	injected into the lumen at increasing pressure until the catheter burst per ISO 10555-1 and the static burst pressure was compared with the maximum pressure generated with manual syringe injection.	
Torque Strength	The catheter was navigated through a clinically relevant tortuous path and with the distal tip secured the proximal end was rotated until failure. [FDA guidance PTA and Specialty Catheters]	Pass
Distal Tip Flexibility	Tip flexibility was measured with a force gauge to measure the compressive force exerted by the side of the catheter at a defined distance from the distal tip when the distal tip of the catheter is deflected. Results were compared to the predicate.	Pass
Particulate	The amount of particulate matter generated during simulated use testing was compared to the predicate. [FDA guidance PTA and Specialty Catheters]	Pass
Coating Lubricity, Durability, and Integrity	Durability and lubricity measured the frictional forces with a pinch test. The hydrophilic coating was examined for damage after simulated use.	Pass
Corrosion	Corrosion resistance evaluated the metallic components related to corrosion contacting the intended fluid path. [ISO 10555-1]	Pass

J. Biocompatibility Testing

No new biocompatibility testing was conducted for the 93 NeuFlex™ Catheter. Biocompatibility assessments for the subject device were adopted from the predicate 87 NeuGlide™ Catheter.

K. Sterilization

The 93 NeuFlex™ Catheter is sterilized using the same validated EO process as the predicate 87 NeuGlide™ Catheter, with a sterility assurance level of $1x10^{-6}$ validated per the overkill method in accordance with ISO 11135, "Sterilization of Health- Care Products - Ethylene Oxide - Requirements for The Development, Validation and Routine Control of a Sterilization Process for Medical Devices".

L. Shelf Life and Packaging

Accelerated aging testing based on ASTM F1980 was conducted to verify packaged device performance to support a 6-month shelf-life claim based on adoption from the predicate 87 NeuGlide Catheter, which uses the same packaging configuration as the subject 93 NeuFlex™ Catheter. Device performance was verified by functional and performance testing following 6-month accelerated aging.

M. Conclusions

The subject 93 NeuFlex™ Catheter and predicate 87 NeuGlide™ Catheter share the same intended use and basic technological characteristics. The differences in technological characteristics do not raise new or different questions of safety or effectiveness of the device. Based on the results of bench performance testing, the subject and predicate devices are substantially equivalent.