October 31, 2023

EOSolutions, Corp.
℅ Garry Koroshec
Senior Design Quality Engineer / Regulatory Affairs
InNeuroCo, Inc.
19700 Sterling Road, Suite 1
Pembroke Pines, Florida 33332

Re: K231629
Trade/Device Name: 091 Balloon Guide Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY, QJP
Dated: October 3, 2023
Received: October 5, 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,

Naira Muradyan -S

Naira Muradyan, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
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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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231629

Device Name
091 Balloon Guide Catheter

Indications for Use *(Describe)*
The 091 Balloon Guide Catheter is indicated for use in facilitating the insertion and guidance of intravascular catheters into a selected blood vessel in the peripheral and neuro vascular systems. The balloon provides temporary vascular occlusion during these and other angiographic procedures. The Balloon Guide Catheter is also indicated for use as a conduit for Retrieval devices.

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

Date Summary Prepared	October 30, 2023
Submitter	InNeuroCo Inc. 19700 Stirling Road, Suite 1 Pembroke Pines, FL 33332 On behalf of: EOSolutions, Corp. 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
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Trade Name	091 Balloon Guide Catheter
Regulation Number	21 CFR 870.1250
Device Common or Classification Name	Percutaneous Catheter, Neurovasculature
Product Class	Class II

Product Panel	Cardiovascular, Neurology
Product Code	DQY, QJP
Predicate Device	091 Balloon Guide Catheter (K220331)
Reference Device	091 Long Sheath (K172468)

6.1 Device Description

The 091 Balloon Guide Catheter is a coaxial-lumen, coil-reinforced, variable stiffness catheter with a balloon at the distal end. A radiopaque marker is included at the distal end of the balloon (at the distal tip of the catheter) for fluoroscopic visualization. A compliant balloon is flush mounted on the distal end of the catheter to provide temporary vascular occlusion during angiographic procedures. A bifurcated luer hub on the proximal end of the catheter allows attachments for flushing, inflation, and aspiration. This catheter is designed for use in facilitating the insertion and guidance of an intravascular catheter into a selected blood vessel in the peripheral and neuro vascular systems. The dimensions and maximum recommended balloon inflation volume for the 091 Balloon Guide Catheter are indicated on the product label. A peel-away introducer, dilator, and one-way luer valve accessory are included within the packaging. A similar dilator was cleared as part of the reference device under K172468. The 091 Balloon Guide Catheter is supplied sterile, non- pyrogenic, and is intended for single use only.

6.2 Indications for Use

The 091 Balloon Guide Catheter is indicated for use in facilitating the insertion and guidance of intravascular catheters into a selected blood vessel in the peripheral and neuro vascular systems. The balloon provides temporary vascular occlusion during these and other angiographic procedures. The Balloon Guide Catheter is also indicated for use as a conduit for Retrieval devices.

6.3 Technological Characteristics and Basis for Substantial Equivalence

Table 6.1 Technological Comparison between the subject 091 Balloon Guide Catheter and 091 Balloon Guide Catheter (K220331)

Parameter	**Predicate Device** **091 Balloon Guide Catheter (K220331)**	**Subject Device** **091 Balloon Guide Catheter (K231629)**
Indications for Use	The 091 Balloon Guide Catheter is indicated for use in facilitating the insertion and guidance of intravascular catheters into a selected blood vessel in the peripheral and neuro vascular systems. The balloon provides temporary vascular occlusion during these and other angiographic procedures. The Balloon Guide Catheter is also indicated for use as a conduit for Retrieval devices.	Same
Anatomical Location	Peripheral and Neuro Vasculature	Same
Product Code	DQY, QJP	Same
Classification	Class II	Same
Regulation Number	870.1250	Same
Catheter Material	Outer Jacket: PTFE and Polyethylene Inner Member: PTFE, Pebax, and Nylon Distal Tip: Chronoflex and Polyolefin	Same

Parameter	Predicate Device 091 Balloon Guide Catheter (K220331)	Subject Device 091 Balloon Guide Catheter (K231629)
Reinforcement Layer	Stainless Steel Coil	Same
Radiopaque Marker Band	Platinum/Iridium	Same
Coating	None	Same
Internal Construction	Co-axial Lumen	Same
Hub	Polycarbonate	Same
Strain Relief	Silicone	Same
Balloon Material	Polyurethane Elastomer	Same
Working Length	95 cm	75, 85, 95 cm
Max Outer Diameter	0.125 inches	Same
Shaft Inner diameter	0.0905 inches	Same
Accessories supplied	Peel Away Introducer	Dilator, One-Way Valve, Peel Away Introducer
Dilator	None	Working Length: 88, 98, 108 cm Inner/Outer Diameter: 0.038 in max/0.087 in
Packaging	Polyethylene Tube and HDPE Packaging Card	Same
	Tyvek/PE/PET Pouch	Same
Sterilization	Ethylene Oxide	Same
Number of Uses	Single Use	Same

6.4 Performance Data

The list of the performance testing conducted to demonstrate that the subject 091 Balloon Guide Catheter meets its performance specifications is presented below in Table 6.2. Verification test data from testing done on previously cleared version of the 091 Balloon Guide Catheter (K220331) were also used to support the new 091 Balloon Guide Catheter.

Table 6.2 – Performance Bench Tests Performed on the 091 Balloon Guide Catheter

Test performed	Test Summary	Results
Design Verification and Validation Testing		
Catheter Tensile Strength	The catheter must meet tensile strength specifications.	**Pass**
Catheter Burst	The catheter must meet catheter burst specification.	**Pass**
Particulate	The catheters were tested in comparison to the predicate device for all particle sizes including the large particles to establish substantial equivalence to the predicate device.	**Pass**
Dilator Working Length	The dilator must meet working length specification.	**Pass**
Dilator Inner Diameter (ID)	The dilator must meet inner diameter (ID) specification.	**Pass**
Dilator Outer Diameter (OD)	The dilator must meet outer diameter (OD) specification.	**Pass**
Dilator Hub Compatibility	The hub luer shall meet the applicable criteria for each test as defined by ISO 594-1 and ISO 594-2.	**Pass**
Dilator Radiopacity	The dilator shall be visible under fluoroscopic imaging.	**Pass**
Dilator Tensile Strength	The dilator must meet tensile strength specifications.	**Pass**
Dilator Visual Inspection	Samples were visually inspected under 2.5X magnification to ensure acceptance criteria were met.	**Pass**
Label Content	The label and directions for use (DFU) must meet content specifications.	**Pass**
Usability – Simulated Use Testing	Simulated use testing was conducted utilizing all accessory devices expected to be used during a clinical procedure.	**Pass**

6.5 Biocompatibility Testing

The 091 Balloon Guide Catheter and the dilator were assessed for biocompatibility in accordance with ISO 10993-1, "Biological evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process," as part of predicate and reference device submissions. There are no material or contact duration changes of these components in the current submission. The subject device is considered an externally communicating medical device with circulating blood contact for less than 24 hours. The results of the prior testing demonstrate the biocompatibility of the 091 Balloon Guide Catheter and the dilator for their indicated use.

6.6 Sterilization Validation

A sterilization validation adoption assessment was conducted to verify that the subject device can be adopted into the previously validated ethylene oxide (EO) sterilization cycle. It concluded that the subject 091 Balloon Guide Catheter will likely present an equal or lesser challenge to the sterilization cycle than the existing products. EO residual testing and bioburden testing of the existing 091 Balloon Guide Catheter and dilator products are deemed applicable to the subject device.

6.7 Clinical Data and Animal Study

No clinical data or animal study were deemed necessary to support the subject device submission.

6.8 Conclusion

The 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 091 Balloon Guide Catheter, is substantially equivalent to the predicate 091 Balloon Guide Catheter (K220331). The differences between the subject and the predicate devices do not raise new questions of safety and effectiveness.