July 29, 2022

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

Re: K220331
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: June 30, 2022
Received: July 1, 2022

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 (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,

Naira Muradyan, Ph.D.
Assistant 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220331

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	July 21, 2022
Submitter	InNeuroCo, Inc. 19700 Stirling Road, Suite 1 Pembroke Pines, FL 33332
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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 Codes	DQY, QJP
Predicate Device	Concentric Balloon Guide Catheter K112404

6.1 Device Description

The 091 Balloon Guide Catheter is a coaxial-lumen, coil-reinforced, variable stiffness catheter with a compliant balloon at the distal end to provide temporary vascular occlusion during angiographic procedures. A radiopaque marker is included at the distal end of the balloon (at the distal tip of the catheter) for fluoroscopic visualization. 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 accessory is included within the packaging. It 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 of the 091 Balloon Guide Catheter and Concentric Balloon Guide Catheter (K112404)

Parameter	Predicate Device Concentric Balloon Guide Catheter (K112404)	Subject Device 091 Balloon Guide Catheter (K220331)
Indications for Use	The Concentric Balloon Guide Catheter is indicated 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 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.	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.
Anatomical Location	Peripheral and neuro vasculature	Peripheral and neuro vasculature
Product Code	DQY	DQY, QJP
Classification	Class II	Class II
Regulation Number	870.1250	870.1250
Catheter Material	Outer Jacket: Pebax Inner Lumen: PTFE and Pebax Distal Tip: Pebax	Outer Jacket: PTFE and Polyethylene Inner Lumen: PTFE, Pebax, and Nylon Distal Tip: Chronoflex and Polyolefin
Reinforcement Layer	Stainless Steel Braid	Stainless Steel Coil
Radiopaque Marker Band	Platinum/Iridium	Platinum/Iridium

Parameter	Predicate Device Concentric Balloon Guide Catheter (K112404)	Subject Device 091 Balloon Guide Catheter (K220331)
Coating	None	None
Internal Construction	Co-axial Lumen	Co-axial Lumen
Hub	Polyurethane	Polycarbonate
Strain Relief	Polyolefin	Silicone
Balloon Material	Silicone	Polyurethane elastomer
Working Length	80cm, 95cm	95cm
Max Outer Diameter	0.088, 0.104, and 0.116 inches	0.125 inches
Shaft Inner Diameter	0.059, 0.078, and 0.085 inches	0.0905 inches
Accessories Supplied	Dilator	Peel Away Introducer
Packaging	Polyethylene Tube and HDPE Packaging Card	Polyethylene Tube and HDPE Packaging Card
	Tyvek/PE/PET Pouch	Tyvek/PE/PET Pouch
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 091 Balloon Guide Catheter meets its performance specifications and demonstrates substantial equivalence to the predicate device. The 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.

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

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**
Balloon Burst	The constrained balloon must not burst below the specified volume.	**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	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**
Balloon Leak Test	Testing was conducted per IS0 10555-4, section 4.4.2 and Annex B.	**Pass**

Test performed	Test Summary	Results
Dimensional Verification	The catheter and introducer must meet dimensional specifications.	**Pass**
Chemical Compatibility	The device shall withstand exposure to saline, dextrose, heparin, and contrast.	**Pass**
Hub Compatibility	Catheter luers shall be tested per ISO 594-1:1986 and ISO 594-2:1998.	**Pass**
Kink Resistance	After conditioning, two sections of each test sample were wrapped around progressively smaller diameter mandrels until a kink was observed.	**Pass**
Balloon Air Purge Test	The balloon shall be capable of having an acceptable level of air removed.	**Pass**
Balloon Fatigue Test	The balloon shall withstand the specified number of inflation/deflation cycles.	**Pass**
Balloon Compliance Test	The balloon shall not exceed the specified dimensions for a given inflation volume.	**Pass**
Flow Arrest	The balloon was inflated within a clinically relevant flow model and a minimum occlusion time (aka time of effective flow arrest) was confirmed.	**Pass**
Balloon Deflation Time	The balloon was inflated within a clinically relevant flow model, the time to restore flow (deflation) was measured.	**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**
Packaging – Seal Width	The seals should meet the specified width.	**Pass**
Design Validation Testing		
In-vitro Simulated Use Study – Benchtop	The 091 Balloon Guide Catheter was prepared per the instructions for use (IFU). A simulated interventional procedure was performed by physicians in order to verify the product's performance.	**Pass**
Usability Testing		
In-vitro Simulated Use Study – Useability (including Label Content - Product IFU)	Evaluators representative of the intended user population shall review the 091 Balloon Guide Catheter IFU and labeling, then attempt to use the catheters and accessories along with the expected compatible products in a simulated use environment, using worst-case neurovascular models.	**Pass**

No clinical studies were required to demonstrate substantial equivalence.

6.5 Biocompatibility testing

The 091 Balloon Guide Catheter was assessed for biocompatibility in accordance with ISO 10993-1, "Biological evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process." The subject device is considered an externally communicating medical device with circulating blood contact for less than 24 hours. The biological effects tests performed are summarized in Table 6.3.

The results of the testing demonstrate the biocompatibility of the 091 Balloon Guide Catheter for its indicated use.

Table 6.3 Summary of Biocompatibility Testing

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

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 (EO) sterilization cycle. The device passed all sterility, EO residual, limulus amebocyte lysate (LAL), and bioburden testing.

6.7 Conclusion

The review of the verification and validation test results as well as the comparison of the device classification, indications for use, operating principles, technological characteristics, sterility, and biocompatibility, demonstrate that the subject device, the 091 Balloon Guide Catheter, is substantially equivalent to the predicate device, the Concentric Balloon Guide Catheter (K112404). The differences between the subject and the predicate devices do not raise new questions of safety and effectiveness.