September 19, 2023

MIVI Neuroscience, Inc.
Srija Reddy Bandari
Regulatory Affairs Specialist
6545 City West Parkway
Eden Prairie, Minnesota 55344

Re: K222948
Trade/Device Name: Q Distal Access Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP, DQY
Dated: August 18, 2023
Received: August 21, 2023

Dear Srija Reddy Bandari:

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 -S

Naira Muradyan, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
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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)*
K222948

Device Name
Q Distal Access Catheter

Indications for Use *(Describe)*
The Q Distal Access Catheter is indicated for use with compatible guide catheters in facilitating the insertion and guidance of microcatheters into a selected blood vessel in the peripheral, coronary and neuro vascular systems.

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 K222948

Date Prepared: 09-18-2023

Table 1. General Information	
510(k) Submitter	**Contact**
MIVI Neuroscience, Inc. 6545 City West Parkway Eden Prairie, MN 55344	Srija Reddy Bandari Regulatory Affairs Specialist Email: sbandari@mivineuro.com Phone: (612) 447-2897 Fax: (952)-944-3488
Trade Name	Q Distal Access Catheter
Common Name	Q Distal Access Catheter
Classification Information	**Percutaneous catheter; 21 CFR 870.1250 (Class II)** **ProCode: QJP, DQY** **Panel: Cardiovascular**
Predicate Device	MIVI Q Distal Access Catheter (K192558)

Device Description

The Q Distal Access Catheter is a single-lumen, variable stiffness catheter with radiopaque markers on the distal and proximal end of the catheter portion for angiographic visualization. The proximal portion of the device is a stainless-steel control wire. The distal portion of the device is a coiled/braided catheter shaft with hydrophilic coating along the entire length to reduce friction during use. The Q Distal Access Catheter may be introduced via an 8F guide catheter/6F guide sheath and over a guidewire/microcatheter into the arterial vasculature until the desired vessel is reached. The pin vise may be used to advance the catheter. The syringe and flush tool components may aid in the flushing of the Q Distal Access Catheter.

Intended Use / Indications for Use

The Q Distal Access Catheter is indicated for use with compatible guide catheters in facilitating the insertion and guidance of microcatheters into a selected blood vessel in the peripheral, coronary and neuro vascular systems.

Substantial Equivalence Comparison

Table 2 compares the intended use and technological characteristics of the subject and predicate devices.

Table 2: Comparison with Currently Marketed Predicate			
Feature		***Subject Device*** **Q Distal Access Catheter**	***Currently Marketed Predicate Device*** **MIVI Q Distal Access Catheter**
510(k) Holder & Manufacturer		MIVI Neuroscience, Inc.	
510(k)#		K222948	K192558
Classification Information		Percutaneous catheter 21 CFR 870.1250 (Class II) ProCode: QJP, DQY; Panel: Cardiovascular	
Indications / Intended Use / Principle of Operation			
Indications / Intended Use		Indicated for use with compatible guide catheters in facilitating the insertion and guidance of microcatheters into a selected blood vessel in the peripheral, coronary and neuro vascular systems.	
Principle of Operation		Used to endovascularly insert and guide microcatheters under fluoroscopy during diagnostic and/ or therapeutic procedures for patients with arterial disease or damage.	
Design Information			
Configuration	Distal	Single-lumen, variable stiffness, braided (5F, 6F) / coiled (3F, 4F)	
	Proximal	Control (push) wire through a guide catheter luer fitting	
	Tip	Straight	
	Radiopaque Markers	Two (2)- Distal and Proximal	
	Catheter Coating	Hydrophilic	
Catheter Sizes		3F, 4F, 5F, 6F	
Catheter Lengths	3F	148 cm	148 cm
	4F	135 cm and 145 cm	135 cm
	5F	130 cm and 140 cm	130 cm

Table 2: Comparison with Currently Marketed Predicate			
Feature		***Subject Device*** **Q Distal Access Catheter**	***Currently Marketed Predicate Device*** **MIVI Q Distal Access Catheter**
	6F	130 cm and 135 cm	130 cm
Guidewire Compatibility (cm)	3F	0.018”	
	4F	0.035”	
	5F		
	6F		
Guide Catheter / Sheath Compatibility (ID)		0.088”- 0.091”	0.088”- 0.090”
Guide Catheter/ Sheath Length Range (cm)		90-100	90-95
Catheter Biomaterials		Patient contacting materials are identical between the subject and currently marketed predicate.	
Accessories / Packaging / Sterilization / Shelf Life / Labeling			
Provided Accessories		Syringe (5 mL) Flush tool (4F/5F)	None
Required Accessories (not provided)		Compatible Y adapter with rotating hemostasis valve (lengths between 6-8 cm)	Same
Package Configuration		Catheter inserted in a plastic tube, placed in PETG tray with lid, and sealed in new Tyvek pouch with improved chevron. Sealed pouch packaged in labeled carton with Instructions for Use.	Catheter inserted in a plastic tube, mounted on an insert card, and sealed in a pouch. Sealed pouch packaged in carton box along with Instructions for Use.
Sterile & Non-pyrogenic?		Yes	
Sterilization Method		Ethylene Oxide (sustainable)	Ethylene Oxide
Shelf Life		3 years	

Non-Clinical Performance Testing

Bench Testing

The modified Q Distal Access Catheter has been evaluated through design verification testing, which confirmed the device met the design specifications as summarized in Table 3 below.

Table 3: Design Verification Testing

Test	Test Method Summary	Results
Label Integrity	Device labels were evaluated to ensure labels are intact and legible after environmental conditioning, distribution simulation and aging.	Pass
Bubble Leak	Device packaging was evaluated to detect gross leaks in packaging.	Pass
Pouch Seal Strength	Pouch was evaluated for the mechanical strength of the seal.	Pass
Coating Particulate	The number and size of particles generated during simulated use were measured.	Pass
Dimensional Verification	Dimensional specifications were verified to ensure device meets all the requirements.	Pass
Tip Inspection	Catheter tip was evaluated to ensure the complete retrieval of tip during its removal.	Pass
Surface Integrity	Device visually inspected to ensure surface is free of defects that can cause tissue trauma.	Pass
Heat shrink Inspection	To ensure heat shrink identifier remains intact and legible after environmental conditioning, distribution simulation and aging.	Pass
Coating Uniformity	To evaluate the devices for uniform coating.	Pass
Simulate Use/ Compatibility	The catheter performance was evaluated when used in conjunction with other devices used in standard procedures without sustaining damage or kinks and without causing damage to the other devices.	Pass
Coating Adhesion	To visually categorize the integrity of coating on the device.	Pass

Push/Track	To ensure device is able to be tracked without kink under normal conditions in tortuous anatomy.	Pass
Kink Resistance	The distal shaft of the device was evaluated for kink resistance when subjected to a bend radius of 1.0 cm.	Pass
Liquid Leak Under Pressure	To ensure device does not exhibit leakage of liquid under a minimum pressure of 44 psi for a minimum of 30 seconds.	Pass
Static Burst	To ensure device withstands a minimum pressure of 100 psi prior to burst.	Pass
Tensile Strength - Push Wire	To ensure device meets the required tensile strength between the push wire and catheter body: 15 N pull force minimum.	Pass
Tensile Strength - Distal Section	To ensure device meets the required tensile strength of the distal section of the shaft: 5N pull force minimum.	Pass

Biocompatibility

The Q Distal Access Catheter patient contacting materials are the same materials used in the currently marketed predicate MIVI Q Distal Access Catheter K192558 with the same patient contact classification. A summary of the additional biocompatibility testing conducted to support the device modifications is included in Table 4 below.

Table 4: Summary of Biocompatibility Testing

Test	Test Method	Conclusion	Result
Cytotoxicity	Extracted with MEM with 10% FBS at 37°C for 24 hours and administered on mouse fibroblast L929 cells.	Biological reactivity Grade 0 on the test article after 48 hrs. incubation with mouse fibroblast. The response on the positive and negative control article extracts confirmed the suitability of the tests. The test article (TA) is considered non-cytotoxic.	Pass

Hemolysis (Direct and Indirect)	ASTM F756, Standard Practice for Assessment of Hemolytic Properties of Materials.	The test article in direct contact with blood had a hemolytic index of 0.3%, and the test article extract had a hemolytic index of 0.2%. Both the test article in direct contact with blood and the test article extract were non-hemolytic.	Pass

Sterilization

The modified Q Distal Access Catheter in the new packaging is sterilized using Sustainable Ethylene Oxide (EO) sterilization process. Sterilization validation was performed in accordance with ISO 11135:2014 to qualify the reduced EO sterilization process developed by Steris AST which is an optimized cycle using less EO sterilant while still achieving the 10^{-6} sterility assurance level (SAL) as an acceptable means of sterilization.

The EO residual, limulus amoebocyte lysate (LAL), and bioburden testing were performed in accordance with standards listed below:

- *ISO 10993-7 Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals.*
- *The USP 24 chapter 85 "Bacterial Endotoxins Test" and FDA guidance, "Pyrogen and Endotoxins Testing: Questions and Answers," June 2012.*

Shelf-life

The modified Q Distal Access Catheter will be labelled with an expiration date of 3 years from the date of sterilization, which is same as for the predicate device K192558.

Conclusions

The modified Q Distal Access Catheter has the same indications for use, principle of operation, and design concept as the currently marketed MIVI Q Distal Access Catheter predicate device. The technological differences between the subject device and the currently marketed predicate device include the catheter dimensions, increased compatibility range with the guide catheter/sheath, addition of the syringe and flush tool accessory components to the packaging configuration, packaging, sterilization, and product labeling updates. The subject device has been evaluated through risk analysis and testing. The differences do not raise new questions of safety or effectiveness. The testing verified the device met the design specifications. Based on the predicate comparison, risk assessment, and device testing information provided in this 510(k) submission, the subject device has been shown to be appropriate for its intended use and is therefore considered substantially equivalent to the predicate device.