December 16, 2021

MIVI Neuroscience, Inc.
Janel Hurtado
Director of Regulatory
6545 City West Parkway
Eden Prairie, Minnesota 55344

Re: K212402
Trade/Device Name: MIVI Q Distal Access Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP, DQY
Dated: November 11, 2021
Received: November 17, 2021

Dear Janel Hurtado:

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)*
K212402

Device Name
MIVI Q Distal Access Catheter

Indications for Use *(Describe)*
The MIVI 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 K212402

[as required by 21 CFR §807.92(c)]

Date Prepared: December 14, 2021

510(k) Submitter	**Contact**
MIVI Neuroscience, Inc. 6545 City West Parkway Eden Prairie, MN 55344 (952) 944-3834	Janel Hurtado Regulatory Affairs Director Email: jhurtado@mivineuro.com (952) 944-3834

General Information	
Trade Name	MIVI Q Distal Access Catheter
Common Name	Distal access catheter
Classification Information	Device Classification: Class II Common Name: Percutaneous catheter Regulation Number: 21 CFR 870.1250 Product Code: QJP; Panel: Neurology Product Code: DQY; Panel: Cardiovascular
Predicate Device	MIVI Q Distal Access Catheter (K192558; April 6, 2020)

Device Description

The MIVI Q Distal Access Catheter (Q 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 catheter shaft has a hydrophilic coating to reduce friction during use. The proximal portion of the catheter is a stainless-steel control (push) wire. The Q 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 Q Docking Station may be used to facilitate insertion and extraction of the Q Catheter through a hemostasis valve attached to the 8F guide catheter/6F guide sheath. The pin vise may be used to advance the catheter.

Intended Use / Indications for Use

The MIVI 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

The MIVI Q Distal Access Catheter (pre-loaded with Docking Station) has identical indications, principle of operation, and similar design as the currently marketed predicate catheters.

Table 1: Comparison with Currently Marketed Predicate		
Feature	***Subject Device*** **MIVI Q Distal Access Catheter**	***Predicate Device*** **MIVI Q Distal Access Catheter**
510(k) Holder & Manufacturer	MIVI Neuroscience, Inc.	
510(k)#	K212402	K192558

Table 1: Comparison with Currently Marketed Predicate				
Feature			***Subject Device*** **MIVI Q Distal Access Catheter**	***Predicate Device*** **MIVI Q Distal Access Catheter**
Classification Information			Percutaneous catheter 21 CFR 870.1250 (Class II) ProCode: QJP, DQY	
Indications / Intended Use / Principle of Operation				
Indications for Use			The MIVI 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.	The Q 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.
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 Docking Station assembly	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	
Total Length (cm)		3F	154	148
		4F	141	135
		5F	136	130
		6F	136	130
Extensible Length				
Extensible length (cm) with:	90 cm Guide	3F	40-42	
		4F	27-29	
		5F	22-24	
		6F	22-24	
	95 cm Guide	3F	35-37	
		4F	22-24	
		5F	17-19	
		6F	17-19	
Control Wire Length			108	104

Table 1: Comparison with Currently Marketed Predicate			
Feature		***Subject Device*** **MIVI Q Distal Access Catheter**	***Predicate Device*** **MIVI Q Distal Access Catheter**
Pin Vise Shape		Looped shape (Pin Vise not removable)	
Guidewire Compatibility (cm)	3F	0.018”	
	4F	0.035”	
	5F		
	6F		
Catheter Biomaterials		Patient contacting materials are identical between the subject and currently marketed predicate and accessories.	
Accessories / Packaging / Sterilization / Shelf Life			
Provided Accessories		9F Rotating Hemostasis Valve Y-Connector	None
Required Accessories (not provided)		8F guide catheter / 6F guide sheath 90-95 cm in length	
Package Configuration		Catheter inserted in a plastic tube, mounted on an insert card, and sealed in a pouch. Sealed pouch packaged in carton along with Instructions for Use.	
Sterile & Non-pyrogenic		Yes	
Sterilization Method		Ethylene Oxide (EO)	
Shelf Life		3 years	

The technological differences between the modified MIVI Q Distal Access Catheter and the currently marketed predicate do not raise new questions of safety and effectiveness.

Non-Clinical Performance Testing

Bench Testing

Bench testing was completed to assess the performance of the subject device, as shown in the following table.

Test	**Test Summary**	**Result**
Dimensional Verification	The device must meet dimensional specifications.	Pass
System Introduction (Simulated Use)	The device must function as intended.	Pass
Liquid Leakage under Pressure	The device must hold a hydrostatic pressure.	Pass
Tensile Strength	Tensile strength pull force minimum must be met.	Pass

Biocompatibility

Biocompatibility testing was completed to assess the subject device, as shown in the following table.

Test	Test Summary	Result
Cytotoxicity	Extracted with MEM with 10% FBS at 37 °C for 24 hours and administered on mouse fibroblast L929 cells.	PASS
Irritation or Intracutaneous Reactivity	Extracted with 0.9% NaCl and cottonseed oil (CSO) at 37 °C for 72 hours and intracutaneously injected in rabbits.	PASS
Sensitization	Extracts: 0.9% NaCl, CSO for 72 hours at 37 °C.	PASS
Acute Systemic Toxicity	Extracted with 0.9% NaCl and CSO at 37 °C for 72 hours and injected in mice.	PASS
Pyrogenicity (Material-mediated)	Extracted with 0.9% NaCl at 37 °C for 72 hours and injected intravenously in rabbits.	PASS
Hemolysis	Extracted from PBS at 37 °C for 24 hours, administered on rabbit blood; or directly contacting rabbit blood in vitro.	PASS
Unactivated Partial Thromboplastin Time	Human plasma was exposed to the test article at a ratio of 6cm2/ml for 15 minutes at 37 °C.	PASS
Complement Activation	Human plasma was exposed to the test article at a ratio of 6 cm2/mL for 90 mins at 37 °C, in triplicate.	PASS

Sterilization

The sterilization method is unchanged. Confirmatory testing on the final packaging configuration was completed and met specification.

Shelf Life and Expiration Dating

The labeled shelf life of the modified device is the same as that of the predicate, 3 years from the date of sterilization. The bench testing described above was performed to support the shelflife of the modified device.

Conclusion

The modified MIVI Q Distal Access Catheter has identical indications, principle of operation, and similar design as the currently marketed MIVI Q Catheter predicate device. The technological differences between the modified Q Catheter and the currently marketed predicate do not raise new questions of safety and effectiveness. Based on the predicate comparison, risk assessment, and device testing results, the modified MIVI Q Distal Access Catheter has been shown to be appropriate for its intended use and is considered substantially equivalent to the predicate device.