April 6, 2020

MIVI Neurovascular
Janel Hurtado
Regulatory Affairs Director
6545 City West Parkway
Eden Prairie, Minnesota 55344

Re: K192558
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: March 12, 2020
Received: March 13, 2020

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,

Xiaolin Zheng, Ph.D., M.S.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192558

Device Name
MIVI Q Distal Access Catheter

Indications for Use *(Describe)*

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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY

Date Prepared: November 8, 2019

Table 1. General Information	
510(k) Submitter	**Contact**
MIVI Neuroscience, Inc. 6545 City West Parkway Eden Prairie, MN 55344	Randy LaBounty Vice President Regulatory, Clinical and Quality Email: rlabounty@mivineuro.com
Trade Name	MIVI Q Distal Access Catheter
Common Name	Distal access catheter
Classification Information	Percutaneous catheter; 21 CFR 870.1250 (Class II) ProCode: QJP, DQY; Panel: Cardiovascular
Predicate Device	MIVI Neuroscience, Inc. MIVI Mi-EXT Extension Catheter (*now branded as the MIVI Q Distal Access Catheter*) (K163233)

Device Description

The MIVI 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 catheter contains a pin vise threaded on the control wire, which may be used to advance the catheter.

Intended Use / Indications for Use

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.

Substantial Equivalence Comparison

Table 2 compares the substantial equivalence of the subject and predicate devices.

Table 2. Comparison with Currently Marketed Predicate		
Feature	***Subject Device* MIVI Q Distal Access Catheter**	***Currently Marketed Predicate Device* MIVI Q Distal Access Catheter**
510(k) Holder & Manufacturer	MIVI Neuroscience, Inc.	

Table 2. Comparison with Currently Marketed Predicate				
Feature			***Subject Device*** **MIVI Q Distal Access Catheter**	***Currently Marketed Predicate Device*** **MIVI Q Distal Access Catheter**
510(k)#			K192558	K163233
Classification Information			Percutaneous catheter 21 CFR 870.1250 (Class II) ProCode: QJP, DQY	
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	
Total Length (cm)		3F	148	163
		4F	135	150
		5F	130	145
		6F	130	145
Extensible Length			Range	Fixed
Extensible Length (cm) with:	90cm Guide	3F	40-42	42
		4F	27-29	29
		5F	22-24	24
		6F	22-24	24

Table 2. Comparison with Currently Marketed Predicate				
Feature			***Subject Device*** **MIVI Q Distal Access Catheter**	***Currently Marketed Predicate Device*** **MIVI Q Distal Access Catheter**
	95cm Guide	3F	35-37	42
		4F	22-24	29
		5F	17-19	24
		6F	17-19	24
Control Wire Length			104 cm	119 cm
Pin Vise Shape			Looped shape (Pin vise not removable)	Straight shape (Pin vise can be removed)
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.	
Accessories / Packaging / Sterilization / Shelf Life / Labeling				
Provided Accessories			None	
Required Accessories (not provided)			8F guide catheter / 6F guide sheath with rotating hemostasis valve with Y adapter and stopcock.	• 8F guide catheter / 6F guide sheath • Y adapter with rotating hemostasis valve (lengths between 6-8 cm)
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	
Labeling			Proposed IFU	Current IFU

Non-Clinical Performance Testing

Bench Testing

Table 3. Design Verification Testing		
Test	**Test Method**	**Results**
Dimensional Verification	Ensure device meets dimensional requirements.	Pass
Corrosion Resistance	Any exposed metallic components must not show signs of corrosion.	Pass
Tensile Strength – Pin Vise	Ensure adequate device tensile strength.	Pass
System Compatibility / Simulated Use	Simulated use testing with "worst case" dimensional stack up.	Pass

Based on the test results, the Q catheter with the described wire modification is considered verified to perform to its design specifications.

Biocompatibility

The MIVI Q Distal Access Catheter patient contacting materials are the same materials used in the currently marketed predicate MIVI Q Catheter K163233 with an identical bio-contact. There is no change to colorants between the subject and predicate devices.

Sterilization

The MIVI Q Distal Access Catheter packaging configuration and packaged device density are the same for the predicate K163233 and subject device. No additional testing or validation is required for the subject device to be adopted into the existing sterilization cycles.

Shelf Life and Expiration Dating

The modified Q catheter will be labeled with an expiration date of 3 years from the date of sterilization, which is the same as the predicate K163233. The change to the length and distal feature of the control (push) wire does not introduce any new materials and does not impact the shelf life of the product.

Substantial Equivalence Summary and Conclusion

The modified MIVI Q Distal Access Catheter has identical indications, principle of operation, and a similar design to the currently marketed MIVI Q catheter predicate device. Based on the predicate comparison, risk assessment, and device testing results, the modified MIVI Q catheter has been shown to be appropriate for its intended use and is therefore considered substantially equivalent to the predicate device. The modified Q catheter raises no new questions of safety or effectiveness compared to the predicate device and is therefore substantially equivalent.