January 27, 2022

MIVI Neurovascular, Inc.
Janel Hurtado
Regulatory Affairs Director
6545 City West Parkway
Eden Prairie, Minnesota 55443

Re: K213771
Trade/Device Name: Merlin Aspiration System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEZ
Dated: November 24, 2021
Received: December 2, 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,

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular 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)*

K213771

Device Name

Merlin Aspiration System

Indications for Use *(Describe)*

- Merlin Aspiration Catheter

As a part of the Merlin Aspiration System, the Merlin Aspiration Catheter is indicated for the removal of fresh, soft emboli and thrombi in the peripheral arterial system.

- High Flow Tubing

As a part of the Merlin Aspiration System, the High Flow Tubing is indicated to connect the guide catheter to an aspiration pump.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY

Date Prepared: January 24, 2022

Table 1. General Information	
510(k) Submitter	**Contact**
MIVI Neuroscience, Inc. 6545 City West Parkway Eden Prairie, MN 55344	Janel Hurtado Regulatory Affairs Director Email: jhurtado@mivineuro.com
General Information	
Trade Name	Merlin Aspiration System
Common Name	Catheter, Embolectomy
Classification Information	Percutaneous catheter; 21 CFR 870.5150 (Class II) ProCode: QEZ Panel: Cardiovascular
Predicate Device	Penumbra INDIGO™ Aspiration System (K161523)
Reference Device	MIVI Q Distal Access Catheter (K192558)

Device Description

The Merlin Aspiration System is comprised of two devices:

- Merlin Aspiration Catheter
- High Flow Tubing

The Merlin Aspiration Catheter is introduced through a guide catheter or long sheath into the peripheral vasculature and guided over a guidewire to the site of primary occlusion. The Merlin Aspiration Catheter is used in conjunction with an aspiration pump, which is connected to High Flow Tubing. These devices are visible under fluoroscopy.

Merlin Aspiration Catheter

The Merlin Aspiration Catheter consists of single lumen, coiled construction, variable stiffness shaft with radiopaque markers on distal and proximal end of the catheter portion for angiographic visualization. The Merlin Aspiration Catheter is identical in design to the MIVI Q Distal Access Catheter (K192558).

Table 2: Device Information	
Device Description	**Model Number**
Merlin Aspiration Catheter, 3F	**M3-36**
Merlin Aspiration Catheter, 4F	**M4-43**

Merlin Aspiration Catheter, 5F	**M5-57**
Merlin Aspiration Catheter, 6F	**M6-69**
High Flow Tubing	**HFT 110**

High Flow Tubing

The MIVI High Flow Tubing is a sterilized and disposable (onetime use) product consisting of high-pressure PVC tubing with end fittings and an on/off switch. The MIVI High Flow Tubing connects an aspiration pump to a reperfusion catheter, providing a means for introducing vacuum during procedures. The MIVI High Flow Tubing has a flow valve that allows the physician to start and stop the flow of aspiration.

Intended Use / Indications

- Merlin Aspiration Catheter

  As a part of the Merlin Aspiration System, the Merlin Aspiration Catheter is indicated for the removal of fresh, soft emboli and thrombus in the peripheral arterial system.

- High Flow Tubing

  As a part of the Merlin Aspiration System, the High Flow Tubing is indicated to connect the guide catheter to an aspiration pump.

Substantial Equivalence Comparison

Table 3 compares the substantial equivalence of the subject, predicate and reference devices.

Table-3: Comparison with Predicate Device			
Feature	***Subject Device*** **Merlin Aspiration System**	***Predicate Device*** **INDIGO Aspiration System**	***Reference Device*** ***MIVI Q Distal Access Catheter***
510(k) Holder & Manufacturer	MIVI Neuroscience, Inc.	Penumbra, Inc.	MIVI Neuroscience, Inc.
510(k)#	K213771	K161523	K192558
Product Code	QEZ	QEW	DQY
Regulatory Class	Class II		
Regulatory Number	21 CFR 870.5150		
Regulatory Name	Percutaneous Catheter		
Indications / Intended Use / Principle of Operation			
Indications / Intended Use	Merlin Aspiration Catheter As a part of the Merlin Aspiration System, the Merlin Aspiration	INDIGO Aspiration Catheters and Separators As part of the Penumbra Embolectomy Aspiration System	Q Distal Access Catheter is indicated for use with compatible guide catheters in facilitating the insertion and guidance of microcatheters into a selected

Table-3: Comparison with Predicate Device			
Feature	***Subject Device*** **Merlin Aspiration System**	***Predicate Device*** **INDIGO Aspiration System**	***Reference Device*** ***MIVI Q Distal Access Catheter***
	Catheter is indicated for the removal of fresh, soft emboli and thrombus in the peripheral arterial systems. High Flow Tubing As a part of the Merlin Aspiration System, the HFT 110 High Flow Tubing is indicated to connect the guide catheter to an aspiration pump.	(INDIGO™ Aspiration System), the INDIGO Aspiration Catheters and Separators are indicated for the removal of fresh, soft emboli and thrombi from vessels of the peripheral arterial and venous systems. INDIGO Aspiration Tubing As part of the Penumbra Embolectomy Aspiration System (INDIGO™ Aspiration System), the INDIGO Sterile Aspiration Tubing is indicated to connect the INDIGO Aspiration Catheters to the Penumbra Pump MAX. Penumbra Pump MAX The Penumbra Pump MAX is indicated as a vacuum source for the Penumbra Aspiration System.	blood vessel in the peripheral, coronary and neuro vascular systems.
Aspiration Catheter			
Tip	Straight	Straight	Straight
Marker band	Radiopaque	Radiopaque	Radiopaque
Catheter Coating	Hydrophilic	Hydrophilic	Hydrophilic
Guidewire compatibility	Yes	Yes	Yes
Catheter Sizes	3F, 4F, 5F, 6F	3.4F, 5F, 6F, 8F	3F, 4F, 5F, 6F

Table-3: Comparison with Predicate Device			
Feature	***Subject Device*** **Merlin Aspiration System**	***Predicate Device*** **INDIGO Aspiration System**	***Reference Device*** ***MIVI Q Distal Access Catheter***
Total Length (cm)	148cm,135cm,130cm,130cm	150cm, 132cm, 135cm, 85cm	148cm,135cm,130cm,130cm
Catheter Biomaterials	Patient contacting materials are listed in Table 11-3 in Section 11.7	Biocompatible, commonly utilized for interventional devices	Same as Merlin Aspiration Catheter
Principle of Operation	The principle of operation is for removal of fresh, soft emboli and thrombi in the peripheral arterial system, using an endovascular approach, under fluoroscopy. Contrast is often used during catheter placement.	The principle of operation is for removal of fresh, soft emboli and thrombi in the peripheral arterial and venous system, using an endovascular approach, under fluoroscopy. Contrast is often used during catheter placement.	Used to endovascularly insert and guide microcatheters under fluoroscopy during diagnostic and/or therapeutic procedures for patients with arterial disease or damage
Aspiration Tubing			
Materials	The materials list is provided in listed in Table 11-3 in Section 11.7	Biocompatible, commonly utilized for interventional devices	N/A
Inner Diameter (ID)	0.110 +/- .003 inches	0.071”- 0.110” [1.8mm – 2.8mm]	N/A
Length	112 +/- 3 inches	112.0 [284.5cm]	N/A
Principle of Operation	The High Flow Tubing is a suction tube used to pass fluids from a catheter to a retention canister based on vacuum applied by a pump. It is connected between a commercially available aspiration catheter and a chosen source of vacuum.	Tubing consists of a short tubing segment with an inline filter, and connectors on each end to facilitate attachment to the pump’s vacuum port. The tubing is provided pre-attached to the canister reservoir lid.	N/A
Accessories / Packaging / Sterilization / Shelf Life / Labeling			
Provided Accessories	Not provided with any accessories.	Torque Device and Introducer Sheath	Not provided with any accessories

Table-3: Comparison with Predicate Device			
Feature	***Subject Device*** **Merlin Aspiration System**	***Predicate Device*** **INDIGO Aspiration System**	***Reference Device*** ***MIVI Q Distal Access Catheter***
Required Accessories	• 9F Rotating hemostasis valve Y-Connector • 8F guide catheter / 6F guide sheath 90-95 cm in length (Required Accessory)	None	• 9F Rotating hemostasis valve Y-Connector • 8F guide catheter / 6F guide sheath 90-95 cm in length (Required Accessory)
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. High Flow Tubing is placed in a sealed, labeled Tyvek pouch packaged in a labeled box.	Commonly utilized for interventional devices	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		
Single use	Yes	Yes	Yes
Labeling	Proposed IFU	Current IFU	Current IFU

Performance Testing

Bench Testing

The Merlin Aspiration System is identical to the MIVI Q Distal Access Catheter (K192558), which has been evaluated through risk analysis and design verification testing, which confirmed the device met design specifications.

Testing includes:

Table 4: Design Verification Testing	
Merlin Aspiration Catheter	
Test	**Result**
Coating Particulate Testing	Met established criteria
Coating Adhesion	Met established criteria

Coating Uniformity	Met established criteria
Surface Integrity	Met established criteria
Tip Inspection	Met established criteria
Liquid Leakage under Pressure	Met established criteria
Dimensional Verification	Met established criteria
Kink Resistance	Met established criteria
Push/Track	Met established criteria
Suction Flow Rate	Met established criteria
System Introduction / Aspiration of Thromboemboli	Met established criteria
Tensile Strength-Push Wire	Met established criteria
Tensile Strength-Distal Section	Met established criteria
Catheter Torque Testing	Met established criteria
Catheter Burst Testing	Met established criteria
High Flow Tubing	
Dimensional Verification	Met established criteria
Vacuum Pressure	Met established criteria
Flow Rate	Met established criteria
Degree of Collapse	Met established criteria
Simulated Use	Met established criteria
Leak Test	Met established criteria
Distal Male Luer Tubing Tensile Strength	Met established criteria
Female Luer Tubing Tensile Strength	Met established criteria
Proximal Male to Tubing Tensile Strength	Met established criteria
Connector to Tubing Tensile Strength	Met established criteria

Animal Testing

The Animal Testing data was performed in the porcine carotid, renal, and subclavian vasculature of 8 animals to ensure that there are no new questions of safety and effectiveness.

Biocompatibility

The MIVI Merlin Aspiration System patient contacting materials are the same materials used in the currently marketed reference device with an identical bio-contact. There is no change to colorants between the subject and reference devices.

Sterilization

Each Merlin Aspiration Catheter and High Flow Tubing device meets EO and ECH limits specified in the ISO 10933-7 *Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals (2008).*

The sterilization validation for Merlin Aspiration Catheter and High Flow tubing was validated in accordance with *ISO 11135-1: 2014 Sterilization of healthcare product– Ethylene oxide – Part 1: Requirements for development validation and routine control of a sterilization process for medical devices (2014).*

Shelf-life and Expiration Dating

The Merlin Aspiration System will be labeled with an expiration date of 3 years from the date of sterilization, which is same as predicate and reference devices. There is no change in materials used and this does not impact the shelf-life of the product.

Substantial Equivalence Summary and Conclusion

The Merlin Aspiration System and the predicate device, the INDIGO Aspiration System, have identical indications, principles of operation, and a comparable design, but the Merlin catheter is indicated only for peripheral arterial use. While there are technological differences between the Merlin Aspiration System and the predicate device which are related to exclusion of separators, product labeling, and size matrix (3-6F and 130-148 cm lengths for the Merlin catheter, 3.4-8F and 85-150 cm lengths for the INDIGO aspiration catheter, 0.110+/- 0.003 inches ID and 112+/-3 inches length for High Flow Tubing, 0.071-0.110 inches ID and 112.0 inches length for INDIGO Aspiration Tubing), the Merlin Aspiration catheter is identical to currently marketed Q Distal Access catheter reference device in design and materials, and the scope of the change includes an indication change and rebranding. Therefore, the Merlin Aspiration Catheter has been evaluated through risk analysis and design verification testing (DVT). The testing verified the device met the design specifications and is sufficiently robust and suitable for its intended use as the predicate device. Based on the predicate device comparison, risk assessment, and DVT information provided in this 510(k), the subject device has been shown to be appropriate for its intended use and is therefore considered substantially equivalent to the predicate device.