



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 9, 2015

MIVI Neuroscience, Inc.
Mr. Randy LaBounty
Vice President Regulatory and Clinical Affairs
6545 City West Parkway
Eden Prairie, MN 55344

Re: K151396
Trade/Device Name: MIVI Mi-Axus™ Guide Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: November 6, 2015
Received: November 9, 2015

Dear Mr. LaBounty:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Carlos L. Pena -S 

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K151396

Device Name

MIVI Mi-Axus™ Guide Catheter

Indications for Use (Describe)

The MIVI Mi-Axus™ Guide Catheter is indicated for use 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

Date Prepared: 28-July-2015

Submitter's Name / Contact Person

Manufacturer

MIVI Neuroscience, INC
6545 City West Parkway
Eden Prairie, MN 55344

Contact Person

Matthew Ogle
President and CEO
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Email: mogle@mivineuro.com

General Information

Trade Name

MIVI Mi-Axus™ Guide Catheter

Common / Usual Name

Guide Catheter

Classification Name

Percutaneous Catheter (21 CFR 870.1250, Product Code DQY)

Regulatory Classification Class

II

Panel

Division of Cardiovascular Devices (DCD)
Peripheral Interventional Devices Branch (PIDB)

Predicate Device(s)

MIVI MI-AXUS 6F Guide Catheter – K140557
Penumbra Neuron™ MAX System – K111380

Device Description

The MIVI Mi-Axus 8F Guide Catheter consists of a single lumen, braided, variable stiffness shaft designed for use in facilitating the insertion and guidance of microcatheters into a selected blood vessel in the peripheral, coronary, or neurovascular system. A radiopaque marker is included on the distal end for angiographic visualization. The catheter shaft has a hydrophilic coating to reduce friction during use. Additionally, the distal segment of the PEBAX shaft of the 8F device is impregnated with Barium Sulfate (BaSO₄) for increased radiopacity. A luer hub on the proximal end allows attachments for flushing, insertion of catheters, and aspiration. It is used in junction with a rotating hemostatic valve with side-arm adapter for flushing, catheter insertion and aspiration. The MIVI Mi-Axus Guide Catheter has a straight distal tip and is available in lengths of 80 or 90 cm and an 8F diameter.

Intended Use / Indications

The MIVI Mi-Axus Guide Catheter is indicated for use in facilitating the insertion and guidance of microcatheters into a selected blood vessel in the peripheral, coronary and neuro vascular systems.



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Principle of Operation

The device will be utilized to endovascularly insert and guide microcatheters under fluoroscopy so that the microcatheters can deliver contrast agents or other devices during diagnostic and/or therapeutic procedures for patients with arterial disease or damage. The subject 8F device will incorporate Barium Sulfate (BaSO₄) into the distal segment of the PEBAX shaft in order to increase radiopacity.

Accessories

There are no accessories to the MIVI 8F Guide Catheters.

Comparison to Predicate Devices:

	Subject Device	Predicate Device	Predicate Device
Feature	MIVI Mi-Axus 8F, 80 or 90cm Guide Catheter	MIVI Mi-Axus 6F 110cm Guide Catheter	Penumbra Neuron Max 8F, 80 or 90cm Guide Catheter. Inner diameter – 0.088”
Classification	II, DQY	II, DQY	II, DQY
Indications for Use	The MIVI 8F Guide Catheter is indicated for use in facilitating the insertion and guidance of microcatheters into a selected blood vessel in the peripheral, coronary and neuro vascular systems.	The MIVI 6F Guide Catheter is indicated for use in facilitating the insertion and guidance of microcatheters into a selected blood vessel in the peripheral, coronary and neuro vascular systems.	The Neuron MAX System is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.
Materials, Packaging and Sterilization			
Shaft Materials	PTFE lined PEBAX with stainless steel braid, PEBAX impregnated with Barium Sulfate (BaSO₄)	PTFE lined PEBAX with stainless steel braid	Catheter Type - Braid reinforced.
Proximal End Configuration	Hub with female luer conical fitting	Hub with female luer conical fitting	



6545 City West Parkway
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	Subject Device	Predicate Device	Predicate Device
Feature	MIVI Mi-Axus 8F, 80 or 90cm Guide Catheter	MIVI Mi-Axus 6F 110cm Guide Catheter	Penumbra Neuron Max 8F, 80 or 90cm Guide Catheter. Inner diameter – 0.088”
Packaging	Catheter attached to an SBS packaging card inside PET/PE/Tyvek pouch, inside SBS box	Catheter attached to an SBS packaging card inside PET/PE/Tyvek pouch, inside SBS box	
Sterilization	Ethylene Oxide	Ethylene Oxide	
Dimensions			
Usable Length	75 ± .5 or 85 ± .5 (cm)	105 ± .5	
Outer Diameter	8F	6F	8F
Proximal ID (mm, inches, F)	2.26mm (0.089”) 6.8F - or - 2.3mm (0.089”) 6.8F	1.6mm (0.063”) 4.8F	
Proximal OD (mm, inches, F)	2.7mm (0.108”) 8F	2.0mm (0.079”) 6F	
Distal ID when hydrated (mm, inches, F)	2.26mm (0.089”) 6.8F -or- 2.3mm (0.089”) 6.8F	1.3mm (0.053”) 3.9F	
Distal OD when hydrated (mm, inches, F)	2.7mm (0.108”) 8F	1.8mm (0.069”) 5.3F	
Luminal Maximum Length	83 or 93	113	
Tip Shape	Straight	Straight	
Radiopaque Shaft Segment	Yes	No	Yes



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Functional Testing:

Design verification testing of the MIVI 8F Guide Catheter consisted of:

Performance Test	Result
Surface Integrity	Met established criteria
Torque Response – Catheter	Met established criteria*
Catheter Kink Resistance – Proximal Section	Met established criteria
Catheter Kink Resistance and Coating Damage – Distal Section	Met established criteria
Catheter – Coating Adhesion	Met established criteria
Catheter – Coating Uniformity	Met established criteria
System - Introduction	Met established criteria
Device Compatibility	Met established criteria
Push/Track - Catheter	Met established criteria
Tip Stiffness	Met established criteria

*Deviation – The original protocol requirements stated that the torque response would be measured in the Tortuous Path Anatomical Model. Based on feedback from the initial FDA submission, the 8F MI-AXUS Catheter was tested using the Farlow’s Glass Model as it is more representative of the distal tortuosity. The model used represents a more challenging condition and would be considered worst case.

Testing for the line extension of the subject MIVI 8F Guide Catheter was conducted in accordance with ISO 10555-1:2013 – Sterile, Single Use Intravascular Catheters.

Biocompatibility:

The predicate 6F MIVI Mi-Axus catheter of the Mi-Axus catheter assembly was previously demonstrated to be biologically safe. The 8F device uses the same materials and manufacturing processes as the predicate device, with the addition of Barium Sulfate (BaSO₄) which is impregnated into the PEBAX of the catheter shaft. Therefore, only a limited number of tests were considered necessary to determine the extractability of the BaSO₄.

Testing was conducted in accordance with EN ISO 10993-1. MIVI Mi-Axus 8F Guide Catheters have been classified according to EN ISO 10993-1:2009, *Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing* as follows:

- Category: Externally Communicating
- Contact type: Circulating blood
- Contact Duration: Limited exposure (≤24 hours)

Based on this classification, tests relevant to the device described within this premarket notification were selected and conducted in accordance with EN ISO 10993-1 and its applicable sub-parts.



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The catheter component of the MIVI Mi-Axus 8F Guide Catheter assembly is the only part of the device that comes in contact with the patient, thus, this is the only item that was assessed. The component successfully passed the following biocompatibility tests:

Test Method	ISO 10993-1 Test Category	Test Method Summary
L929 MEM Elution Test – ISO	Cytotoxicity	Non-Cytotoxic
Hemolysis – Rabbit Blood Direct and Indirect Contact – ASTM	Hemocompatibility (Hemolysis)	Non-Hemolytic

The following was performed to assess the amount of Barium that could be extracted and whether it is within acceptable limits.

Test Method	ISO 10993-18 Test Category
Material Qualification in support of ISO 10993-18 – Non -GLP	Extraction

A toxicological risk assessment was conducted to determine whether repeated patient exposure to the levels of extractables from the test article, could produce unacceptable human health risks.

The report concluded the following:

- Since all surfaces of the device were extracted under exaggerated conditions, the extraction conditions and ratios represented the worst case scenario with respect to the leachable chemicals.
- Overall, test results indicated that the device is biocompatible. Specifically, cytotoxicity and hemocompatibility results met the specified requirements.
- All extractables, including an unknown compound from the semi-volatile organic scan in hexane extract, were lower than their recommended or calculated tolerable intake (TI) levels, resulting in margins of safety (MOS) that are greater than one (i.e. at least 10-fold greater, as MFs varied, based on the applied uncertainty factors).
- The overall risk profile of the Guide Catheter 8FR with BaSO₄ is considered to be acceptable for the intended patient population and duration of use.

Sterilization and Residuals:

The MIVI 8F Guide Catheter meets ethylene Oxide (EO) and ethylene chlorohydrin (ECH) residuals specified in EN ISO 10993-7:2008, Biological Evaluation of Medical Devices – Part 7:



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Ethylene Oxide Sterilization Residuals. A sterility assurance level (SAL) of 10^{-6} will be demonstrated.

Summary of Clinical Performance Data

Not Applicable - No clinical data was needed to demonstrate substantial equivalence to the predicate devices.

Conclusion

MIVI Neurosciences has determined its 8F Guide Catheter to be substantially equivalent to the current legally marketed predicate devices because of the following:

1. Intended use and indications for use are the same as for the predicate devices.
2. There is no difference in the fundamental scientific technology of the devices.
3. The risk assessments and successful verification testing including testing to EN ISO 10555-1, raise no new questions of safety and effectiveness.