



Food and Drug Administration
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November 16, 2015

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

Re: K151825
Trade/Device Name: Viradius™ Neurowire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: MOF, DQX
Dated: October 13, 2015
Received: October 14, 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 

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)
K151825

Device Name
Viradius™ Neurowire

Indications for Use (Describe)

The Viradius™ Neurowire is intended for selective placement of catheters within the neuro and peripheral vasculature.

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 – K151825

Manufacturer: MIVI Neuroscience, Inc.
6545 City West Parkway
Eden Prairie, MN 55344

Contact Person: Matt Ogle
President and CEO
Telephone: 952-944-3834

Date Summary Prepared October 12, 2015

Trade Name of Device: Viradius™ Neurowire

Common Name of Device: Guidewire

Classification of Device: 21 CFR 870.1330 – Class II

Product Code: MOF - Primary
DQX - Secondary

Predicate Device: NeuroScout Steerable Guidewire, 510(k)#: K100351

Performance Data: The following bench testing was performed in support of the Viradius Neurowire and to establish substantial equivalence to the NeuroScout Steerable Guidewire:

- Bond and Joint Tensile Strength
- Torque Response
- Ultimate Torque Reponse
- Tip Deflection
- Push Track
- Surface Integrity
- Guidewire Diameter
- Guidewire Length
- Catheter Compatibility
- Kink Resistance
- Flex Test
- Distal Fracture Test
- Tip Bending and Retention
- Device Coating Adhesion

- Corrosion Test
- Coating Integrity – Simulated Use

A Design Validation study was performed on the bench model to assess the usability of the Viradius Neurowire compared to the previously cleared NeuroScout Steerable Guidewire. Biocompatibility testing, sterilization and one year accelerated aging study was also performed. No clinical studies were performed as there are no change to the indications for use or the fundamental scientific technology of the device.

Conclusion: The Viradius Neurowire is substantially equivalent to the currently cleared NeuroScout Steerable Guidewire based on the successful completion of non-clinical bench and design validation testing as well as similar principles of design, operation and indications for use.

Device Description

The Viradius™ Neurowire consists of a stainless steel wire core and a radiopaque platinum/tungsten coil on the distal tip. The distal section of the guidewire is coated with a hydrophilic coating and the proximal portion of the device is coated with a hydrophobic coating. The guidewire is inserted into a polyethylene hoop and then placed along with a torque device into a labeled poly/tyvek pouch and ethylene oxide sterilized. The pouch, along with an Instruction for Use paper insert is placed into a labeled shipping box.

Indication for Use

The Viradius™ Neurowire is intended for selective placement of catheters within the neuro and peripheral vasculature.

Device Comparison

The table below provides a comparison of the technological characteristics of the Viradius

	Viradius Neurowire	NeuroScout Steerable Guidewire (K100351)	Rationale for Difference (If Present)
Indication for Use	The Viradius™ Neurowire is intended for selective placement of catheters within the neuro and peripheral vasculature.	The NeuroScout Steerable Guidewire is intended for selective placement of microcatheters and other devices within the neuro and peripheral vasculature.	Similar indications, included devices tested with the Viradius Neurowire.
Materials			
Core Material	Stainless Steel	Stainless Steel	N/A

	Viradius Neurowire	NeuroScout Steerable Guidewire (K100351)	Rationale for Difference (If Present)
Coil Material	Platinum/Tungsten	Platinum/Tungsten	N/A
Coil to Core Bond Material	Silver Braze	Adhesive	Bench testing indicated similar tensile strength.
Coating/Distal	Hydrophilic	Hydrophilic	The materials used for the Viradius Neurowire were shown to be biocompatible per ISO 10993 testing. Materials of this type are widely used in similar medical devices.
Coating/Proximal	Polytetrafluoroethylene (PTFE)	Hydrophilic	
Dimensions			
Distal Diameter	0.012"	0.011"	Distal diameter needs to be equal or less than proximal diameter for catheter compatibility.
Proximal Diameter	0.014"	0.014"	N/A
Overall Length	205 cm / 300 cm	205 cm / 300 cm	N/A
Coil Length	18 cm	10 cm	Extension of the flexible coil length.
Other Device Comparisons			
Radiopaque Marker	No discrete marker Platinum Coil at distal tip	No discrete marker Platinum Coil at distal tip	N/A
Tip Shape/Configuration	Straight	Straight	N/A
Sterility Method	Ethylene Oxide	Ethylene Oxide	N/A
Package	Hoop placed in Breathable Pouch	Hoop placed in Breathable Pouch	N/A

Sterilization and Shelf Life

The packaged Viradius Neurowire is sterilized using a validated ethylene oxide (EO) sterilization cycle. The sterilization cycle has been validated to ensure a sterility assurance level (SAL) of 10^{-6} in accordance with ISO 11135-1:2007.

Aging studies for the Viradius Neurowire have established the product and packaging remain functional and maintain sterility for up to one year. Aging studies for packaging integrity, seal strength and device functionality were performed and met all acceptance

criteria.

Biocompatibility

Biocompatibility testing was performed in compliance with AAMI/ANSI/ISO 10993-1:2009. All studies were conducted in compliance with U.S. Food and Drug Administration Good Laboratory Practice (GLP) regulations set forth in 21 CFR part 58.

Test	Result
Cytotoxicity	Pass
Sensitization	Pass
Intracutaneous Reactivity	Pass
Systemic Toxicity (Acute)	Pass
Material Medicated Pyrogen	Pass
Hemocompatibility	Pass

Performance Testing – Bench

A summary of the pre-clinical bench testing performed on the Viradius Neurowire is presented in the table below.

Test	Method	Conclusion
Bond and Joint Tensile Strength	The guidewire, including all joints, must not suffer damage when subjected to tensile force.	All devices met acceptance criteria.
Ultimate Torque Response	The guidewire must withstand a minimum complete rotations without physical damage.	All devices met acceptance criteria.
Torque Response	Distal tip rotation shall be equivalent to predicate guidewire.	All devices met acceptance criteria.
Tip Deflection	Tip deflection force shall be comparable to selected competitor guidewires.	All devices met acceptance criteria.
Push Track – Anatomical Model	Force required to advance guidewire through simulated tortuous neurovascular arteries shall be comparable to predicate device.	All devices met acceptance criteria.
Surface Integrity	Guidewire surface shall not have any particulate visible to the naked eye under close inspection without magnification.	All devices met acceptance criteria.
Guidewire Diameter	The diameter was measured.	All devices met acceptance criteria.
Guidewire Length	The length was measured.	All devices met acceptance criteria.
Catheter Compatibility	Guidewire shall be compatible with microcatheters, distal access catheters, guide catheters, and fluids.	All devices met acceptance criteria.
Kink Resistance	Proximal shaft shall not kink when subjected to a bend radius.	All devices met acceptance criteria.
Flex Test	In accordance with ISO 11070:2014 8.5 the guidewire shall not fracture, loosen, or fail in such a manner that any section of the coil is left free to stretch, a sharp, or potentially traumatic fracture	All devices met acceptance criteria.

	surface is exposed, any part of the device becomes separated such that it would not be removable by withdrawing the device from use, or coated guidewires show flaking of the coating.	
Distal Fracture Test	In accordance with ISO 11070:2014 8.4 the guidewire shall not fracture, loosen, or fail in such a manner that any section of the coil is left free to stretch, a sharp, or potentially traumatic fracture surface is exposed, or any part of the device becomes separated such that it would not be removable by withdrawing the device from use.	All devices met acceptance criteria
Tip Bending and Retention	After insertion through a competitive microcatheter, the bend radius shall not degrade.	All devices met acceptance criteria
Device Coating Adhesion	After simulated use, the guidewire coating shall not exhibit any scratches, flaking, or generate any loose coating material.	All devices met acceptance criteria
Particulate Testing	The guidewire was evaluation for particulate generation under simulated use in a representative tortuous model	Number and size of particulates generated was adequate
Corrosion Test	The guidewire shall not exhibit visual corrosion when immersed in sodium chloride solution followed by boiling distilled or deionized water.	All devices met acceptance criteria

Performance Testing – Animal

No animal study was performed as there is no change to the indications for use or the fundamental scientific technology for the Viradius Neurowire. Substantial equivalence of the Viradius Neurowire has been established to the predicate device through the results of bench testing.

Performance Testing – Clinical

No clinical study was performed as there is no change to the indications for use or the fundamental scientific technology for the Viradius Neurowire. Substantial equivalence of the Viradius Neurowire has been established to the predicate device through the results of bench and design validation testing.