April 28, 2023

Biomerics NLE
% Jonathan Holmes
Senior Manager, Regulatory Affairs
MedVenture Health
299S Main St., Suite 2300
Salt Lake City, Utah 84111

Re: K221390
Trade/Device Name: BNLE Access Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter guide wire
Regulatory Class: Class II
Product Code: DQX
Dated: April 14, 2023
Received: April 14, 2023

Dear Jonathan Holmes:

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,

Kenneth J. Cavanaugh -S

Kenneth J. Cavanaugh Jr., Ph.D.
Deputy Director
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.

Submission Number *(if known)*

K221390

Device Name

BNLE Access Guidewire

Indications for Use *(Describe)*

The BNLE Access Guidewire is intended for percutaneous entry of peripheral vessels using the Seldinger Technique. This device is not intended for use in the coronary or cerebral 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.

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

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510(k) SUMMARY

Submitter:
Jonathan Holmes
Senior Manager, Regulatory Affairs
MedVenture Health
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Manufacturer Contact:
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VP of Engineering and Operations, MN
Biomerics NLE
10351 Xylon Avenue N., Suite 100
Brooklyn Park, MN 55445

DATE PREPARED: May 12, 2022

NAME OF MEDICAL DEVICE:

Proprietary Name:	BNLE Access Guidewire
Common/Usual Name:	Guidewire
Classification Name:	Wire, Guide, Catheter

DEVICE CLASSIFICATION:

Classification Panel:	Cardiovascular
Regulatory Class:	Class II
Product Code:	DQX
Regulation Number:	21 CFR 870.1330

PREDICATE DEVICE:

Proprietary Name:	VSI Guidewire
Common/Usual Name:	Guidewire
Classification Name:	Wire, Guide, Catheter
510(k) Number:	K112631

DEVICE DESCRIPTION:

The BNLE Access Guidewires are available in 40 cm to 80 cm lengths and in the 0.018" – 0.021" diameter range. The BNLE Access Guidewires are available with Nitinol or Stainless Steel (SS) shafts and in configurations with SS coils or radiopaque Tungsten coils.

The BNLE Access Guidewires consist of a solid core shaft with a ground tapered section at the distal end of the guidewire. A micro-coil is wound with a lumen that is then placed over the tapered distal section. The distal end is secured to the shaft via a weld and the proximal end is bonded to the shaft using adhesive. The micro-coil will provide tip radiopacity in designated models. The finished guidewire is placed in a protective polymer dispenser hoop for either sterile packaging in a labeled Tyvek pouch or shipped in bulk non-sterile condition to use with in a procedure tray by a customer.

INTENDED USE/INDICATION FOR USE:

Intended Use: The BNLE Access Guidewire is intended for percutaneous entry of peripheral vessels using the Seldinger Technique. This device is not indicated for use in the coronary or cerebral vasculature.

Indications for Use: The BNLE Access Guidewire is indicated for percutaneous entry of peripheral vessels using the Seldinger Technique. This device is not indicated for use in the coronary or cerebral vasculature.

TECHNOLOGICAL COMPARISON TO PREDICATE DEVICE:

Feature	VSI Guidewire K112631 (Predicate Device)	BNLE Access Guidewire (Subject Device)	Discussion
Class	II	II	Identical
Product Code	DQX	DQX	Identical
Regulation (FDA)	21 CFR 870.1330	21 CFR 870.1330	Identical
Indications for Use	The VSI Guidewire is indicated for percutaneous entry of peripheral vessels using the Seldinger Technique. This device is not indicated for use in the coronary or cerebral vasculature.	The BNLE Access Guidewire is intended for percutaneous entry of peripheral vessels using the Seldinger Technique. This device is not indicated for use in the coronary or cerebral vasculature.	Identical
Wire Diameter	.018"	.018" - .021"	Substantially Equivalent, within current legally marketed brackets for this type of device
Device Length	40cm – 130cm	40cm – 80cm	Substantially Equivalent, within brackets of predicate device

Feature	VSI Guidewire K112631 (Predicate Device)	BNLE Access Guidewire (Subject Device)	Discussion
Tip Type and Shape	Straight, Angled	Straight	Substantially Equivalent, within brackets of predicate device
Wire Material	Stainless Steel, Nitinol	Stainless Steel, Nitinol	Identical
Coating Material, Length and Location	None, PTFE Coated	None	Substantially Equivalent
Tip Material	Stainless Steel, Tungsten	Stainless Steel, Tungsten	Identical
Accessories	May be supplied in a Micro-Introducer Access Kit	None	Substantially Equivalent
Packaging Configuration	5 or 10 pack	5 pack	Substantially Equivalent
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Identical
Shelf Life	≥2 years	1 year	Substantially Equivalent

PERFORMANCE TESTING

The BNLE Access Guidewire was thoroughly tested and verifies that it performs as designed and is suitable for its intended use.

Performance Testing included the following:

- Simulated Use/Device Compatibility
- Corrosion
- Kink Resistance
- Tip Flexibility
- Radiopacity
- Tensile
- Dimensional
- Visual Inspection
- Reverse Bend / Flex
- Fracture Resistance
- Torqueability
- Torque Strength
- Shelf Life

Biocompatibility per ISO 10993-1 for an external communicating device, limited (<24 hour) blood contacting device.

- Cytotoxicity - L929 MEM Elution
- Maximum Sensitization
- Irritation – Intracutaneous Reactivity
- Systemic Toxicity
- Material Mediated Pyrogen
- Hemolysis – Extract and Direct Contact
- ASTM Partial Thromboplastin
- Complement Activation Assay
- Thrombogenicity in Canine
- Chemical Characterization

BNLE Access Guidewire raised no new concerns regarding safety or efficacy.

CONCLUSION:

The BNLE Access Guidewire has been demonstrated to be substantially equivalent in design, materials, sterilization, principles of operation, performance, and indications for use to the predicate, VSI Guidewire (K112631).