June 11, 2020

Penumbra, Inc.
Matthew Benenati
Regulatory Affairs Specialist II
One Penumbra Place
Alameda, California 94502

Re: K201271
Trade/Device Name: Benchmark BMX96 System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP, DQY
Dated: May 11, 2020
Received: May 12, 2020

Dear Matthew Benenati:

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)*
K201271

Device Name
Benchmark BMX96 System

Indications for Use *(Describe)*
The Benchmark BMX96 System is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro 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

K201271

(as required by 21 CFR 807.92)

Pursuant to Section 12, Part (a)(i)(3A) of the Safe Medical Devices Act of 1990, Penumbra, Inc. is providing the summary of Substantial Equivalence for the subject Benchmark BMX96 Access System

1.1 Submitter

Penumbra, Inc.
One Penumbra Place
Alameda, CA 94502 USA

Contact Person:
Matthew Benenati
Regulatory Specialist II
Tel: (510) 995-9705
Fax: (510) 217-6414
E-mail: mbenenati@penumbrainc.com

Date of Preparation: June 9, 2020

1.2 Subject Device

Benchmark BMX96 System

Regulatory Class: II
Classification Panel: Neurology
Classification Name: Percutaneous Catheter
Regulation Number: 21 CFR 870.1250
Product Codes: QJP, DQY

1.3 Predicate Device

Neuron MAX System (K111380)

This predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

1.4 Device Description

The Benchmark BMX96 System is a three-component system comprised of the Benchmark BMX96 Delivery Catheter, Neuron 6F Select Catheter, and a Dilator. The

Benchmark BMX96 Delivery Catheter can be used individually with a 0.038 in. [0.97 mm] guidewire or together with the Neuron 6F Select Catheter to access the desired anatomy.

Benchmark BMX96 Delivery Catheter

The Benchmark BMX96 Delivery Catheter is a single lumen, variable stiffness catheter with a radiopaque marker band on the distal end and a Luer hub on the proximal end. The Benchmark BMX96 Delivery Catheter dimensions are included on the individual device label. The Benchmark BMX96 Delivery Catheter is compatible with introducer sheaths appropriately sized for the outer diameter of Benchmark BMX96.

Neuron 6F Select Catheter

The Neuron 6F Select Catheter is a single lumen, braid-reinforced, variable stiffness catheter with a radiopaque distal end and a Luer hub on the proximal end. The Neuron 6F Select Catheter is available in four tip shapes (SIM, H1, BER, or SIM-V). The Neuron 6F Select Catheter tip shape and dimensions are included on the individual device label. The Neuron 6F Select Catheter is compatible with the Benchmark BMX96 Delivery Catheter.

Dilator

The Dilator is a single lumen, radiopaque catheter with a tapered distal end and a Luer hub on the proximal end. The Dilator is compatible with the Benchmark BMX96 Delivery Catheter. The Dilator facilitates the percutaneous entry of the Benchmark BMX96 Delivery Catheter by forming an atraumatic transition from the skin through the subcutaneous tissue to the vessel.

The Benchmark BMX96 System is a single-use, ethylene oxide (EO) sterilized system.

The Benchmark BMX96 System should be used in interventional procedures by trained physicians.

1.5 Indications For Use

The Benchmark BMX96 System is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.

1.6 Comparison of Technological Characteristics with the Predicate Device

The subject device Benchmark BMX96 System has similar technological characteristics to the previously cleared predicate device. At a high level, the subject and predicate devices are based on the following same technological elements:

- Delivery Catheter dimensions (outer diameter (OD), maximum effective length, distal flexible length)
- Delivery Catheter tip shapes
- Sterilization method (EO)
- 36-month shelf life

The following technological differences exist between the subject and predicate devices:

- Stainless steel hypotube shaft reinforcement (replaced braided coil reinforcement)
- Catheter Inner Diameter (0.096 in.)
- Shorter effective length options
- Slightly longer hydrophilic coating length
- Modified catheter extrusions to include additional polyurethane and polyether block amide materials
- Dilator OD, length

1.7 Performance Data

The following performance data were provided in support of the substantial equivalence determination.

- Design Verification
- Biocompatibility
- Shelf Life
- Sterilization
- Packaging

The subject device met all established requirements.

1.7.1 Design Verification Testing

- Dimensional/Visual Testing
- Friction Testing
- Fluoroscopy Testing
- Simulated Use Testing (Flow Model and Vessel Entry)
- Particulate Testing
- Hub Air Aspiration Testing

- Tensile and Elongation Testing
- Burst Testing
- Corrosion Resistance
- Shelf life
- Packaging
- Sterilization in accordance with ISO 11135 and ISO 10993-7

1.7.2 Biocompatibility

The biocompatibility evaluation for Benchmark BMX96 System was conducted in accordance with ISO 10993-1, USP standards, and FDA Good Laboratory Practices (GLP) as recognized by FDA. The battery of testing included the following tests:

- In vitro Cytotoxicity (MEM Elution)
- Sensitization: Magnusson-Kligman Method
- Irritation: Intracutaneous Toxicity
- Systemic Toxicity: Acute Systemic Injection
- Systemic Toxicity: Material Mediated Pyrogen
- Hemocompatibility
    - In vitro Thrombogenicity
    - Prothrombin Time (PT)
    - Partial Thromboplastin Time (PTT)
    - Complement Activation
    - Hemolysis (indirect contact)
    - Hemolysis (direct contact)

Biocompatibility test results demonstrate biological safety per ISO 10993 and USP requirements.

1.7.3 Performance Data – Animal, Clinical

No animal or clinical study was conducted as bench testing was determined sufficient for verification and validation purposes.

1.8 Conclusions

The subject Benchmark BMX96 System is substantially equivalent to the predicate device Neuron MAX. The subject device has identical intended use as the predicate device. The device testing described in the 510(k) Summary demonstrate the subject devices are substantially equivalent to the predicate device in regard to operating principle, design concept, fundamental technology and device performance.