



August 18, 2022

Penumbra, Inc.  
Buu Buu Ly  
Regulatory Affairs Specialist III  
One Penumbra Place  
Alameda, California 94502

Re: K213390  
Trade/Device Name: Benchmark BMX96 Access System  
Regulation Number: 21 CFR 870.1250  
Regulation Name: Percutaneous Catheter  
Regulatory Class: Class II  
Product Code: QJP, DQY  
Dated: July 13, 2022  
Received: July 15, 2022

Dear Buu Buu Ly:

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Naira Muradyan, Ph.D.  
Assistant 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

## Indications for Use

510(k) Number (if known)

K213390

Device Name

Benchmark BMX96 Access System

Indications for Use (Describe)

The Benchmark BMX96 Access 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**

(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**

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Date of preparation:  
June 01, 2022

### **1.2 Subject Device**

Benchmark BMX96 Access System

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

### **1.3 Predicate Device**

Benchmark BMX96 System (K201271)

### **1.4 Device Description**

The Benchmark BMX96 Access 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, laser-cut hypotube-reinforced, 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 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 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.

## **1.5 Indications For Use**

The Benchmark BMX96 Access 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 and predicate devices have identical technological characteristics.

The only difference between the subject and predicate devices are additional instructions added to the instructions for use (IFU) for the subject device related to radial access use.

## **1.7 Performance Data**

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

- Bench-top Performance.

The subject device met all established requirements.

### **1.7.1 Bench-top Performance**

The following bench-top performance tests were performed on the subject device and all have met acceptance criteria:

- Particulate Testing and Coating Integrity Testing.
- Simulated Use Testing.

### **1.7.2 Biocompatibility**

The subject Benchmark BMX96 Access System is categorized as a limited exposure ( $\leq 24$  hours), externally communicating device with circulating blood contact in accordance with ISO 10993-1. The design and manufacturing of the subject Benchmark BMX96 Access System use identical materials, similar processing, and identical sterilization methods as products that Penumbra has already successfully conducted biocompatibility testing for per ISO 10993-1. Therefore, no additional biocompatibility testing is required.

### **1.7.3 Performance Data – Animal, Clinical**

No animal or clinical studies were conducted because bench testing was determined sufficient for verification and validation purposes.

## **1.8 Conclusions**

The subject Benchmark BMX96 Access System is substantially equivalent to the predicate device Benchmark BMX96 System. The subject device has the same indications for use as the predicate device. The device testing described in this 510(k) Summary demonstrates that the subject device is substantially equivalent to the predicate device in regard to operating principle, design concept, fundamental technology, and device performance. The changes to the instructions for use do not raise new questions of safety and effectiveness.