May 27, 2022

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

Re: K212838
Trade/Device Name: Benchmark Intracranial Access System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP, DQY
Dated: April 27, 2022
Received: April 29, 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) 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

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.

510(k) Number *(if known)*
K212838

Device Name
Benchmark™ Intracranial Access System

Indications for Use *(Describe)*
The Benchmark Intracranial 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™ Intracranial Access System

1.1 Submitter

Penumbra, Inc.
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Date of preparation:

May 26, 2022

1.2 Subject Device

Benchmark Intracranial 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 Intracranial Access System (K142321)

No reference devices were used in this submission.

1.4 Device Description

The Benchmark Intracranial Access System is designed to aid the physician in accessing the target vasculature during interventional procedures. The Benchmark Intracranial

Access System is composed of a Delivery Catheter used for introduction of interventional devices and a corresponding Select Catheter. Use of the Benchmark Intracranial Access System facilitates navigation to the target vascular location and delivery of interventional devices. The Benchmark Intracranial Access System devices are compatible with off-the-shelf accessories. Various lengths and distal shapes of both the Benchmark Delivery Catheter and 5F Select Catheter are provided for physician convenience.

Intended users for the Benchmark Intracranial Access System are physicians who have received appropriate training in interventional techniques. The devices are provided sterile, non-pyrogenic, and are intended for single use only.

The Benchmark Intracranial Access System will be available in two packaging configurations:

- The Benchmark Delivery Catheter is individually packaged.
- The Benchmark Delivery Catheter is pre-packaged with a 5F Select Catheter (K083125).

1.5 Indications For Use

The Benchmark Intracranial 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 the acceptance criteria:

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

1.7.2 Biocompatibility

The subject Benchmark Intracranial Access System is categorized as a limited exposure (≤ 24 hours), externally communicating device with circulating blood contact in accordance with ISO 10993-1. The design and manufacturing of the subject Benchmark Intracranial 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 Intracranial Access System is substantially equivalent to the predicate device Benchmark Intracranial Access System. The subject device has the same indications for use as the predicate device. The device testing described in the 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.