Penumbra, Inc.
Anush Puvvada
Regulatory Affairs Specialist III
One Penumbra Place
Alameda, California 94502

August 31, 2020

Re: K202251
Trade/Device Name: Penumbra System (Penumbra JET 7 Reperfusion Catheter with Xtra Flex Technology; Penumbra JET 7MAX)
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NRY
Dated: August 7, 2020
Received: August 10, 2020

Dear Anush Puvvada:

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 (Acting)
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

1. 510(k) Summary

K202251

(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 Penumbra System® (Penumbra JET™ 7 Reperfusion Catheter with Xtra Flex Technology; Penumbra JET™ 7MAX).

1.1. Sponsor/Applicant Name and Address

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

Contact Person:
Anush Puvvada Regulatory Specialist III
Tel: (510) 440-5568
Fax: (510) 217-6414
E-mail: ypuvvada@penumbrainc.com

Date of Preparation: August 31, 2020

1.2. Subject Device

Penumbra System® (Penumbra JET™ 7 Reperfusion Catheter with Xtra Flex Technology; Penumbra JET™ 7MAX)

Regulatory Class: II
Classification Panel: Neurology
Classification Name: Percutaneous Catheter
Regulation Number: 21 CFR 870.1250
Product Code: NRY (Catheter, Thrombus Removal)

1.3. Predicate Device Information

Penumbra System® Reperfusion Catheter JET™ 7 (K190010)

Penumbra System® [JET™ 7 Reperfusion Catheter with MAX Delivery Device (JET™ 7MAX)] (K191946).

1.4. Device Description

The Penumbra System Reperfusion Catheter Penumbra JET 7 with Xtra Flex technology (JET 7 Xtra Flex) is a component to the currently available Penumbra System. The JET 7

Xtra Flex delivers aspiration from the Aspiration Pump directly to the site of occlusion to assist in the removal of thrombus from the neurovasculature. The devices are provided sterile, non-pyrogenic, and intended for single use only.

The Penumbra System Penumbra JET 7MAX is an additional configuration to the currently available Penumbra System. The MAX Delivery Device is an optional accessory for use with the JET 7 Xtra Flex and is removed prior to aspiration.

1.5. Indications For Use

Penumbra Reperfusion Catheters and Separators

As part of the Penumbra System, the Reperfusion Catheters and Separators are indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral – M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.

Penumbra 3D Revascularization Device

As part of the Penumbra System, the Penumbra 3D Revascularization Device is indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral – M1 and M2 segments) within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.

Penumbra Aspiration Tubing

As part of the Penumbra System, the Penumbra Sterile Aspiration Tubing is indicated to connect the Penumbra Reperfusion Catheters to the Penumbra Aspiration Pump.

Penumbra Aspiration Pump

The Penumbra Aspiration Pump is indicated as a vacuum source for Penumbra Aspiration Systems.

1.6. Comparison of Technological Characteristics with the Predicate Device

There are no differences in the technological characteristics between the subject device and predicate device. The changes made to the subject device are solely labeling changes for more clarity to include additional warnings, precautions, and instructions to enhance the safety of device use.

1.7. Performance Data

There are no differences in technological characteristics between the subject and predicate devices and therefore no verification and validation studies were required.

1.8. Conclusions

The subject Penumbra System® (Penumbra JET™ 7 Reperfusion Catheter with Xtra Flex Technology; Penumbra JET™ 7MAX) are substantially equivalent to the predicate devices, the Penumbra System (Reperfusion Catheter JET 7) (K190010) and the Penumbra System [JET 7 Reperfusion Catheter with MAX Delivery Device (JET 7MAX)] (K191946). The subject devices have identical intended use and technological characteristics as their corresponding predicate devices. Also, there are no changes in terms of device performance, safety, operating principle, design concept, fundamental technology manufacturing, and packaging between the subject and predicate devices. Therefore, the subject devices are substantially equivalent to their respective predicates.