March 14, 2025

Penumbra, Inc.
Samyukta Rangachari
Regulatory Affairs Specialist
One Penumbra Place
Alameda, California 94502

Re: K250079
Trade/Device Name: Ruby XL System
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular Embolization Device
Regulatory Class: Class II
Product Code: KRD
Dated: January 10, 2025
Received: January 13, 2025

Dear Samyukta Rangachari:

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 (the 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 available 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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new

premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Finn E. Donaldson -S

Digitally signed by Finn E. Donaldson -S
Date: 2025.03.14 09:04:35 -04'00'

Finn Donaldson
Acting Assistant Director
DHT2C: Division of Coronary and Peripheral Intervention Devices
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250079

Device Name
Ruby XL System

Indications for Use *(Describe)*
The Ruby XL System is indicated for arterial and venous embolizations in the peripheral 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

1. Submitter

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

Contact Person:
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Regulatory Affairs Specialist III
Phone: (763) 742-9306
Email: srangachari@penumbrainc.com

Date of Preparation: January 10, 2025

2. Subject Device

Ruby XL System

Regulatory Class:	II
Classification Panel:	Cardiovascular
Classification Name:	Vascular embolization device
Regulation Number:	21 CFR §870.3300
Product Code:	KRD

3. Predicate/Reference Devices

510(k) Number	Name of Device
Predicate	
K173614	Penumbra Coil System (Penumbra Coil 400 and Ruby Coil System) and POD System

4. Predicate Comparison

Table 1: Predicate Comparison

Attributes	Predicate Device	Subject Device
General		
Trade Name	Penumbra Coil System (Penumbra Coil 400 and Ruby Coil System); POD System	Ruby XL System
510(k) No.	K173614	K250079
Indications for use	Indicated for the embolization of: • Intracranial aneurysms • Other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae • Arterial and venous embolizations in the peripheral vasculature	Indicated for arterial and venous embolizations in the peripheral vasculature.
Classification	Class II, HCG & KRD	Class II, KRD
Materials/Construction		
Coil Implant	Platinum/Tungsten, Adhesive, Titanium, Polymer	SAME
Introducer Sheath	Polymer	SAME
Dimensions/Shape		
Coil Secondary Shape	Complex, Finish	SAME
Coil Length	Appropriately Sized For Target Vasculature	SAME
Coil Primary Diameter		
Coil Secondary Diameter		
Detachment Pusher Length		
Detachment Mechanism	Mechanical	SAME
Other		
Sterilization Method, SAL	Ethylene Oxide, $>10^{-6}$	SAME
Method of Supply	Sterile, single use only	SAME
Device Packaging Materials and Dimensions	As specified in K173614	SAME

5. Device Description

The Ruby XL System is comprised of a platinum embolization coil attached to a composite delivery pusher, and the Penumbra Detachment Handle. The coil/delivery pusher is packaged separately from the Penumbra Detachment Handle.

6. Indications for Use

The Ruby XL System is indicated for arterial and venous embolizations in the peripheral vasculature.

7. Summary of Non-Clinical Data/Performance Data

Included in this section are summary descriptions of the testing which substantiates the performance of the subject Ruby XL System.

7.1 Summary of Performance Testing – (Bench-Top) Testing

The following bench-top performance (design verification) tests were used in support of the subject device to determine substantial equivalence:

- Dimensional/Visual
- Packaging Inspection, Leak and Seal Strength Testing
- Radiopacity Testing
- Friction Testing
- Fatigue Resistance Testing
- Torsional Resistance Testing
- Stiffness Testing
- Simulated Use and Compatibility Testing
- Corrosion Testing
- Tensile Testing
- MRI Compatibility Testing

7.2 Summary of Biocompatibility

Biocompatibility was evaluated for the subject device in accordance with ISO 10993-1 and the FDA Guidance for Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process".

The following endpoints were evaluated in support of the subject device to determine substantial equivalence:

- Cytotoxicity Testing
- Sensitization Testing
- Irritation Testing
- Systemic Toxicity: Acute Systemic Injection Testing & Material Mediated Pyrogenicity Testing
- Subacute/Subchronic Toxicity Testing
- Genotoxicity Testing
- Implantation Testing
- Hemocompatibility Testing
- Chronic Toxicity Testing
- Carcinogenicity Assessment

7.3 Summary of Shelf-Life

The shelf-life of the subject device is established for 12 months based on accelerated aging data.

8. Summary of Performance Data – Animal, Clinical

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

9. Summary of Substantial Equivalence

The subject Ruby XL System is substantially equivalent to the predicate device with regards to intended use, operating principle, design concept, fundamental technology, and device performance.