DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 2, 2015

Penumbra, Inc.
Mr. Charles DeNault
Regulatory Affairs Specialist III
One Penumbra Place
Alameda, California 94502

Re: K152840
Trade/Device Name: Lantern™ Delivery Microcatheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: October 30, 2015
Received: November 2, 2015

Dear Mr. DeNault:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152840

Device Name
Lantern™ Delivery Microcatheter

Indications for Use *(Describe)*

Lantern Delivery Microcatheter is intended to assist in the delivery of diagnostic agents, such as contrast media, and therapeutic devices, such as occlusion coils, to the peripheral 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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1 510(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 Lantern™ Delivery Microcatheter.

1.1 Sponsor/Applicant Name and Address

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

1.2 Sponsor Contact Information

Charles DeNault
Regulatory Affairs Specialist III
Phone: (510) 748-3302
Fax: (510) 217-6414
Email: cdenault@penumbrainc.com

1.3 Date of Preparation of 510(k) Summary

October 30, 2015

1.4 Device Trade or Proprietary Name

Lantern™ Delivery Microcatheter

1.5 Device Classification

Regulatory Class:	II
Classification Panel:	Cardiovascular
Classification Name:	Catheter, percutaneous
Regulation Number:	21 CFR 870.1250
Product Code:	DQY

1.6 Predicate Device

510(k) Number	Clearance Date	Name of Predicate Device	Name of Manufacturer
K100826	January 13, 2010	PX 400 Delivery Microcatheter	Penumbra, Inc.

1.7 Predicate Comparison

Attribute	Predicate Device	Subject Device
Device name	PX 400 Delivery Microcatheter	Lantern Delivery Microcatheter

Attribute	Predicate Device	Subject Device
Device name	PX 400 Delivery Microcatheter	Lantern Delivery Microcatheter
Classification	Class II, DQY	Same
Indications for Use	Intended to assist in the delivery of diagnostic agents, such as contrast media, and therapeutic devices, such as occlusion coils, to the peripheral and neuro vasculature.	Same
Shaft materials	Nylon, Polyether block amide	Same
Hub materials	Nylon	Same
ID Band	Polyolefin, PET	Same
Strain Relief	Stainless Steel	Same
Marker band materials	Pt/Ir	Same
Coating	Hydrophilic	Same
Effective length	150 cm	80, 110, 115, 130, 135, 150, 160 cm
Proximal outer diameter	0.045 in. max	0.040 in. max
Distal outer diameter	0.040 in. max	0.037 in. max
Inner diameter	0.025 in. min	Same
Packaging materials	Polyethylene, PET, Polyester, Tyvek	Same
Packaging configuration	Individual catheter in tray, pouch, and box	Individual catheter in tray, or hoop attached to packaging card, pouch, and box
Sterilization	EO	Same
Shelf life	36 months	Same

1.8 Device Description

Lantern Delivery Microcatheter is a single lumen intravascular catheter designed to aid physician in accessing distal vasculature. When used in conjunction with a guide catheter and guide wire, Lantern provides access to the target site. Once in place it provides a reinforcing conduit for other intravascular devices.

1.9 Indications for Use/Intended Use

Lantern Delivery Microcatheter is intended to assist in the delivery of diagnostic agents, such as contrast media, and therapeutic devices, such as occlusion coils, to the peripheral and neuro vasculature.

1.10 Summary of Non-Clinical Data

Included in this section is a description of the testing, which substantiates the safe and effective performance of the Lantern Delivery Microcatheter as well as its substantial equivalence to the predicate device:

- Biocompatibility
- Design Verification (Bench-Top Testing)
- Sterilization
- Shelf life

The subject Lantern Delivery Microcatheter met all predetermined requirements.

1.10.1 Biocompatibility Testing

Biocompatibility testing previously performed on the predicate device substantiates the biocompatibility of Lantern. Studies were selected in accordance with EN ISO 10993-1 guidelines (Biological Evaluation of Medical Devices). All studies were conducted pursuant to 21 CFR, Part 58, Good Laboratory Practices. The following tests were performed:

Test	Acceptance Criteria	Results
In vitro Cytotoxicity (MEM Elution)	Sample extracts must yield cell lysis grade ≤ 2	Grade: 1 (slight)
Sensitization (Magnusson-Kligman Method)	Test Group shall yield Grade < 1 score on Magnusson and Kligman scale (provided Control Grade < 1)	Non-sensitizing
Irritation (Intracutaneous Reactivity)	The difference in the mean test article and mean control score must be grade 1.0 or lower	Non-irritant
Systemic Toxicity (Acute)		
Acute Systemic Injection	Sample extracts must not cause significant biological reaction greater than control. That is: • Death in 2 or more animals • Toxic signs (i.e. convulsions, prostration) • Weight loss > 10% in 3 or more animals	Non-toxic
Material Mediated Rabbit Pyrogen	Sample extracts must not cause a total rise in body temperature of ≥ 0.5° C	Non-pyrogenic
Hemocompatibility		
Hemolysis – Indirect Contact	Sample extracts must be nonhemolytic (≤2% hemolytic index)	Non-hemolytic
Complement Activation	The concentrations of C3a and SC5b-9 in the test samples are statistically similar to the predicate control and statistically lower than the positive control for all exposure times	No greater biological response than corresponding control

Test	Acceptance Criteria	Results
Thrombosis (Dog Thrombogenicity)	Device must be non-thrombogenic after 4 hours *in vivo* when compared to control device	Non-thrombogenic

1.10.2 Bench-top Testing

Testing was based on the design specifications, risk analysis and available guidance documents. These guidance documents include:

- Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters (FDA – 1995)
- EN ISO 10555-1:2013,*Sterile, single-use intravascular catheters – Part 1: General Requirements.*

The physical and mechanical properties of Lantern Delivery Microcatheter were assessed using standard test methods and pre-determined acceptance criteria. Devices used for mechanical testing were assembled and packaged in the controlled production environment and sterilized twice using an ethylene oxide sterilization cycle. All established acceptance criteria were met. The following tests were performed:

- Packaging inspection
- Dimensional/visual inspection
- Inspection of design features
- Hub/ air aspiration
- Steam shaping
- Kink resistance
- Simulated use
- Torsion
- Corrosion
- Particulate
- Friction
- Static burst pressure
- Tensile / elongation

All testing met specification. The results of the tests appropriately address the physical and mechanical performance expectations of the device. Based on these overall results, the physical and mechanical properties of the Lantern Delivery Microcatheter are acceptable for the intended use and substantially equivalent to the predicate device.

1.11 Sterilization

The Lantern Delivery Microcatheter is sterilized using a validated EO sterilization process in accordance with EN ISO 11135-1:2014, *Sterilization of Health Care Products – Ethylene Oxide – Part 1: Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices*. Sterilization validation is based on prior testing performed with the modified predicate device.

1.12 Pyrogenicity

The Lantern Delivery Microcatheter has established to be non-pyrogenic based on the prior material mediated rabbit pyrogen biocompatibility testing performed on the predicate, and LAL validation testing performed on the modified predicate. In the LAL validation, three lots of the longest effective length modified predicate were tested for inhibition via the kinetic turbidimetric test method. All three lots met the acceptance criteria of < 2.15 EU/ device. Therefore, production lots of both the predicate device and Lantern are routinely monitored to ensure < 2.15 EU/ device with existing LAL validation.

1.13 Shelf life

The Lantern Delivery Microcatheter has established a shelf life of 36 months based on prior testing performed with the modified predicate device.

1.14 Summary of Substantial Equivalence

The Lantern Delivery Microcatheter is substantially equivalent to the predicate devices with regard to intended use, operating principle, design concept, materials, shelf-life, packaging, and sterilization processes.