October 21, 2023

phenox Limited
Rachel McDaid
Senior Regulatory Affairs Specialist
Kamrick Court, Ballybrit Business Park,
Galway H91 XY38,
Ireland

Re: K231539
Trade/Device Name: pRESET LITE Thrombectomy Device
Regulation Number: 21 CFR 882.5600
Regulation Name: Neurovascular Mechanical Thrombectomy Device for Acute Ischemic Stroke Treatment
Regulatory Class: Class II
Product Code: POL, NRY
Dated: September 22, 2023
Received: September 22, 2023

Dear Rachel McDaid:

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.

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.

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,

Naira Muradyan -S

Naira Muradyan, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
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and Neurodiagnostic Devices
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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)*
K231539

Device Name
pRESET LITE Thrombectomy Device

Indications for Use *(Describe)*

1. The pRESET LITE Thrombectomy Device is indicated for use to restore blood flow in the neurovasculature by removing thrombus for the treatment of acute ischemic stroke to reduce disability in patients with a persistent, proximal anterior circulation, large vessel occlusion, and smaller core infarcts who have first received thrombolytic therapy. Endovascular therapy with the device should be started within 6 hours of symptom onset.

2. The pRESET LITE Thrombectomy Device is indicated to restore blood flow by removing thrombus from a large intracranial vessel in patients experiencing ischemic stroke within 8 hours of symptom onset. Patients who are ineligible for thrombolytic therapy or who fail thrombolytic therapy are candidates for treatment.

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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Traditional 510(k) pRESET® LITE Thrombectomy Device

510(k) Summary (21 CFR 807.92)

K231539

I. SUBMITTER

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Date Prepared: 20th October 2023

II. DEVICE

Device Trade Name: pRESET® LITE Thrombectomy Device
Common or Usual Name: Neurovascular Mechanical Thrombectomy Device for Acute Ischemic Stroke Treatment; Catheter, Thrombus Retriever
Classification: Class II device according to 21 CFR 882.5600; 21 CFR 870.1250
Product Code: POL, NRY
Review Panel: Neurology

III. PREDICATE DEVICE

Device Name: pRESET® Thrombectomy Device
Manufacturer: phenox Limited
510(k) Number: K222848

IV. DEVICE DESCRIPTION

The pRESET® LITE Thrombectomy Device is designed to restore blood flow in the neurovasculature by mechanical removal of thrombus in patients experiencing acute ischemic stroke due to large vessel occlusion with thrombus. The device is designed for use in large vessels of the neurovasculature such as the internal carotid artery (ICA) and the middle cerebral artery (MCA). The device is supplied sterile and intended for single use only.

Traditional 510(k) pRESET® LITE Thrombectomy Device

Materials of Use: See table below for details of the materials used in the construction of the pRESET® LITE Thrombectomy Device.

Table 1: Materials used in the construction of the pRESET® LITE Thrombectomy Device

Component	Material
Retrieval Structure	Nitinol
Push-Wire	Nitinol
Connector Shell	Nitinol
Marker coils	Platinum/Iridium
Shrink Tubing	PTFE
Introducer Sheath	HDPE

V. INDICATIONS FOR USE

Comparison of Indications for Use for the pRESET ® LITE Thrombectomy Device and predicate device pRESET® Thrombectomy Device.

Table 2: Indications for Use for the pRESET® LITE Thrombectomy Device and pRESET® Thrombectomy Device

Parameter	**Predicate Device (K222848)** pRESET® Thrombectomy Device	**Subject Device (K231539)** pRESET® LITE Thrombectomy Device
Indications for Use	1. The pRESET Thrombectomy Device is indicated for use to restore blood flow in the neurovasculature by removing thrombus for the treatment of acute ischemic stroke to reduce disability in patients with a persistent, proximal anterior circulation, large vessel occlusion, and smaller core infarcts who have first received thrombolytic therapy. Endovascular therapy with the device should be started within 6 hours of symptom onset. 2. The pRESET Thrombectomy Device is indicated to restore blood flow by removing thrombus from a large intracranial vessel in patients experiencing ischemic stroke within 8 hours of symptom onset. Patients who are ineligible for thrombolytic therapy or who fail thrombolytic therapy are candidates for treatment.	1. The pRESET LITE Thrombectomy Device is indicated for use to restore blood flow in the neurovasculature by removing thrombus for the treatment of acute ischemic stroke to reduce disability in patients with a persistent, proximal anterior circulation, large vessel occlusion, and smaller core infarcts who have first received thrombolytic therapy. Endovascular therapy with the device should be started within 6 hours of symptom onset. 2. The pRESET LITE Thrombectomy Device is indicated to restore blood flow by removing thrombus from a large intracranial vessel in patients experiencing ischemic stroke within 8 hours of symptom onset. Patients who are ineligible for thrombolytic therapy or who fail thrombolytic therapy are candidates for treatment.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Table 3. Comparison of technological characteristics of the pRESET® LITE Thrombectomy Device and pRESET® Thrombectomy Device

Parameter	Predicate Device	Subject Device
Trade Name	pRESET® Thrombectomy Device	pRESET® LITE Thrombectomy Device
510(k) Number	K222848	K231539
Product Classification	II	II
Classification Regulation	21 CFR 882.5600, 21 CFR 870.1250	21 CFR 882.5600, 21 CFR 870.1250
Product Code	POL, NRY	POL, NRY
Principle of Operation	The device is used in the neurovasculature to restore blood flow for treatment of acute ischemic stroke.	The device is used in the neurovasculature to restore blood flow for treatment of acute ischemic stroke.
Device Sizes	4x20mm 5x40mm 6x30mm	4x20mm 3x20mm
Materials	Retrieval Structure- Nitinol Markers- Platinum/Iridium Push Wire- Stainless Steel Shrink Tubing- PTFE	Retrieval Structure- Nitinol Markers- Platinum/Iridium Push Wire- Nitinol Shrink Tubing- PTFE
Use	Sterile, Single Use	Sterile, Single Use
Sterilization Method	Ethylene Oxide	Ethylene Oxide
Packaging	Stored within dispenser coil, Tyvek pouch, and shipping carton.	Stored within dispenser coil, Tyvek pouch, and shipping carton.

VII. PERFORMANCE DATA

BIOCOMPATIBILITY

Biocompatibility testing was conducted based on International Organization for Standardization (ISO) 10993-1:2018: "*Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process*" and the US FDA guidance document "Use of International Standard ISO 10993, 'Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process'" (2020). Results confirmed the pRESET® LITE Thrombectomy Device is biocompatible.

The biocompatibility evaluation of the pRESET® LITE Thrombectomy Device included relevant data sources related to component material history of safe biological use and testing, and where applicable, safe previous use in previously cleared product and testing. In addition, Table 4 below summarizes testing performed on the pRESET® LITE Thrombectomy Device.

Table 4. Biocompatibility Test Results for the pRESET® LITE Thrombectomy Device

Biological Effect	Test Name	Conclusions
Cytotoxicity	ISO MEM elution - L929 fibroblast cultures method	Non-cytotoxic
Hemocompatibility	Hemolysis (ASTM Method) direct contact	No hemolysis indicated
	Hemolysis (ASTM Method) indirect extract	No hemolysis indicated

STERILIZATION

The pRESET® LITE Thrombectomy Device is sterilized by Ethylene Oxide gas. The sterilization cycle has been validated to ensure a sterility assurance level (SAL) of 10^{-6} in accordance with the EN ISO 11135:2014 & A1:2019 and AAMI TIR28:2016.

SHELF LIFE

Aging studies have established the pRESET® LITE Thrombectomy Device packaging remains functional and maintains sterility for up to 3 years. Aging studies for packaging integrity, seal strength and device functionality were performed and met acceptance criteria.

NON-CLINICAL PERFORMANCE DATA

Non-clinical testing was completed to support the substantial equivalence determination to the predicate. The tests are summarized below.

Performance Testing - Bench

The following bench testing was performed to support substantial equivalence.

Table 5. Performance Test Results for the pRESET® LITE Thrombectomy Device

Test Name	Description	Conclusions
Simulated Use	It shall be possible to safely and reliably prepare, deploy and retract the device in a nominal and worst-case 3D model as described in the instructions for use without damage to the device.	Pass

Simulated Clot Retrieval	It shall be possible to retrieve synthetic clots from a 3D neurovascular model as described in the instructions for use.	Pass
Kink Resistance	It shall be possible to deploy the device to the intended location without kinking of the device.	Pass
Dimensional Verification	Expanded outer diameter (OD) Retriever device length Working length of retrieval device Effective length of retrieval device Diameter of heat shrink Uncovered length Marker position System length	Pass
Radial Force	The relative Chronic Outward Force (RCOF) in the labeled vessel diameters must meet acceptance criteria.	Pass
Austenitic Finish (A_f) Transition Temperature	The A_f transition temperature shall be appropriate for clinical use.	Pass
Radiopacity	Proximal and distal ends of the retrieval device must be radiopaque.	Pass
System Surface Finish	The external surface of the effective length of the device shall appear free from extraneous matter, process and surface defects.	Pass
Device Deployment	It shall be possible to safely and reliably deploy the device as described in the instructions for use without damage to the device.	Pass
Retraction into the Microcatheter	It shall be possible to advance a representative microcatheter over the deployed device, at the site of deployment, until it is fully contained within the inner lumen of the microcatheter without damage to the device.	Pass
Delivery and Re-sheathing Forces	The maximum delivery and re-sheathing forces measured during simulated use clinical conditions.	Pass
Re-Sheathing	It shall be possible to re-sheath the device, as described in the instructions for use, after it has been prepared, deployed and retracted as described in the instructions for use.	Pass
System Tensile Strength	The minimum tensile strength of the thrombectomy system is evaluated to the acceptance criteria.	Pass
Torque Strength	The system must not break after 3 full rotations of the insertion wire.	Pass
Ancillary Device Compatibility	The device shall be compatible with ancillary devices as listed in the Directions for Use (DFU).	Pass

Performance Testing - Animal

No animal testing was required to support substantial equivalence.

Clinical Data

No clinical testing was required to support substantial equivalence.

VIII. CONCLUSIONS

phenox Limited has demonstrated that the pRESET® LITE Thrombectomy Device is substantially equivalent to the pRESET® Thrombectomy Device (K222848) based on the same intended use, similar technological characteristics, similar materials, and the same operating principle. The differences in technological characteristics do not raise new questions of safety or effectiveness. Substantial equivalence is also supported by bench testing.