February 28, 2025

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

Re: K242676
Trade/Device Name: pRESET Delta Thrombectomy Device and pRESET Delta 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: January 30, 2025
Received: January 30, 2025

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.

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,

Naira Muradyan -S

Naira Muradyan, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional, 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242676

Device Name
pRESET Delta Thrombectomy Device and pRESET Delta LITE Thrombectomy Device

Indications for Use *(Describe)*

1.The pRESET Delta Thrombectomy Device and pRESET Delta LITE Thrombectomy Device are 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 Delta Thrombectomy Device and pRESET Delta LITE Thrombectomy Device are 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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510(k) Summary (21 CFR 807.92 (c))

K242676

I. SUBMITTER

phenox Limited,
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H91 XY38

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Date Prepared: 26th February 2025

II. DEVICE

Device Trade Name: pRESET® Delta Thrombectomy Device and pRESET® Delta 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 DEVICES

Device Name: pRESET® Thrombectomy Device and pRESET® LITE Thrombectomy Device
Manufacturer: phenox Limited
510(k) Number: K222848 and K231539

IV. DEVICE DESCRIPTION

Device Description:

The pRESET Delta Thrombectomy Device and pRESET Delta LITE Thrombectomy Device are 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 middle cerebral artery (MCA).

The device is supplied sterile and intended for single use only.

Materials of Use:

See table 1 below for details of the materials used in the construction of the pRESET Delta Thrombectomy Device Product Family (which consist of the pRESET Delta Thrombectomy Device and pRESET Delta LITE Thrombectomy Device).

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

Component	pRESET® Delta Thrombectomy Device	pRESET® Delta LITE Thrombectomy Device
Retrieval Structure	Nitinol	Nitinol
Push-Wire	Stainless Steel Wire	Nitinol
Connector Shell	Nitinol	Nitinol
Marker Coils	Platinum/Iridium	Platinum/Iridium
Body Markers	Platinum/Iridium	Platinum/Iridium
Shrink Tubing	PTFE	PTFE
Introducer Sheath	HDPE	HDPE

V. INDICATIONS FOR USE

Please see Table 2 below for comparison of indications for use between subject devices and predicate devices.

Table 2: Indications for Use of pRESET® Delta Thrombectomy Device Product Family and predicate devices

Parameter	Predicate Devices (K222848, K231539) pRESET Thrombectomy Device and pRESET LITE Thrombectomy Device	Subject Devices pRESET Delta Thrombectomy Device and pRESET Delta LITE Thrombectomy Device
Indications for Use	1. The pRESET® Thrombectomy Device and pRESET® LITE Thrombectomy Device are 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 and pRESET® LITE Thrombectomy Device are 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® Delta Thrombectomy Device and pRESET® Delta LITE Thrombectomy Device are 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® Delta Thrombectomy Device and pRESET® Delta LITE Thrombectomy Device are 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

The comparison of technological characteristics between the subject devices and predicate devices is summarized in Table 3 below:

Table 3: Comparison of technological characteristics of the pRESET® Delta and predicate devices

Parameter	Predicate Devices	Subject Devices
Trade Name	pRESET® Thrombectomy Device pRESET® LITE Thrombectomy Device	pRESET® Delta Thrombectomy Device pRESET® Delta LITE Thrombectomy Device
510(k) Number	K222848 K231539	K242676
Product Classification	Class II	Class 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 LITE 3x20mm LITE	4x20mm 5x40mm 6x30mm 4x20mm LITE 3x20mm LITE
Materials	Retrieval Structure- Nitinol Markers- Platinum/Iridium Push Wire- Stainless Steel/Nitinol Shrink Tubing- PTFE	Retrieval Structure- Nitinol Markers (including Body Markers)- Platinum/Iridium Push Wire- Stainless Steel/Nitinol Shrink Tubing- PTFE
Use	Sterile, Single Use	Sterile, Single Use
Sterilization	Ethylene Oxide	Ethylene Oxide
Shelf Life	3 years	3 years
Packaging Configuration/ Components	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 ISO 10993-1: "*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 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*"."

Results confirmed the pRESET Delta devices are biocompatible.

The biocompatibility evaluation of the pRESET® Delta 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 (K222848, K231539). In addition, Table 4 below summarizes additional testing performed on the pRESET® Delta devices.

Table 4: Summary of biocompatibility testing results for the pRESET® Delta

Test	Test Description	Conclusion
Cytotoxicity ISO 10993-5	MTT Cytotoxicity	Non-cytotoxic
Hemocompatibility ISO 10993-4	ASTM Hemolysis Direct Contact	No hemolysis indicated
	ASTM Hemolysis Extract Method	No hemolysis indicated

STERILIZATION

The pRESET® Delta Thrombectomy Device Product Family 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.

The sterilization cycle has been validated via the half cycle method.

SHELF LIFE

Aging studies were conducted to establish the pRESET® Delta Thrombectomy Device Product Family 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

The following non-clinical performance tests were performed to support the substantial equivalence determination.

Performance Testing - Bench

The following bench testing was carried out on pRESET® Delta Thrombectomy Device Product Family to support substantial equivalence. The results of this testing demonstrated compliance to all the design attributes and that the device performs as intended and the acceptance criteria have been satisfied.

The tests are summarized in Table 5 below.

Table 5: Summary of bench testing performed to support substantial equivalence

Test Title	Specification	Conclusions
Packaging Inspection	Corrugated shipper provides adequate protection to the carton, pouch, and device.	Pass
	Shelf carton provides adequate protection to the pouch and device.	
	Sterile pouch provides adequate protection and sterile barrier to the device.	
Relative Chronic Outward Force (RCOF)	The relative chronic outward force (RCOF) in the labeled vessel diameters must meet acceptance criteria.	Pass
Dimensional	The expanded outer diameter (OD) of the retriever device.	Pass
	The diameter of the body markers.	Pass
	The length of the body markers.	Pass
Simulated Use	It shall be possible to safely and reliably prepare, deploy, and retract the device 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	The device system must have the ability to be delivered to the intended site without any kinking of the insertion wire.	Pass
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
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
Ancillary Device Compatibility	The device shall be compatible with ancillary devices as listed in the Directions for Use (DFU).	Pass
Particulate Analysis	Number and size of particulates generated by device during simulated use shall be comparable to predicate device.	Pass
Radiopacity	Proximal end, distal end, and the body markers of the retrieval device must be radiopaque.	Pass

Standards utilized in bench testing:
ASTM F640-23 "Standard Test Methods for Determining Radiopacity for Medical Use"

FDA guidance documents utilized in bench testing:
"Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions" (2019)
"Applying Human Factors and Usability Engineering to Medical Devices" (2016)

Performance Testing - Animal

No animal testing was required to support substantial equivalence.

Clinical Testing

No clinical testing was required to support substantial equivalence.

VIII. CONCLUSIONS

phenox Limited has demonstrated that the pRESET® Delta Thrombectomy Device and the pRESET® Delta LITE Thrombectomy Device are substantially equivalent to the respective predicate devices, the pRESET® Thrombectomy Device (K222848) and the pRESET® LITE Thrombectomy Device (K231539).
The pRESET® Delta Thrombectomy Device and pRESET® Delta LITE Thrombectomy Device have the same intended use, similar technological characteristics, same materials, and the same operating principle as the pRESET Thrombectomy Device and pRESET LITE Thrombectomy Device. Substantial equivalence is supported by bench performance, biocompatibility, and shelf-life testing.