January 15, 2026

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

Re: K251357
Trade/Device Name: Esperance pHLO Aspiration System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NRY
Dated: December 9, 2025
Received: December 9, 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, PhD
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)*
K251357

Device Name
Esperance pHLO Aspiration System

Indications for Use *(Describe)*
As part of the Esperance pHLO Aspiration System, the Esperance pHLO Aspiration Catheter with a compatible aspiration pump and the Esperance Aspiration Tubing Set 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, basilar, and vertebral arteries) within 8 hours of symptom onset. Patients who are ineligible for thrombolytic drug therapy or who failed thrombolytic drug 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.

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510(k) Summary (21 CFR 807.92)

K251357

I. SUBMITTER

phenox Ltd.,
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Galway, Ireland, H91 XY38

Contact Person: Rachel McDaid
Phone: +353 (0)91 740128
Date Prepared: December 12th, 2025

II. DEVICE

Device Trade Name: Esperance pHLO Aspiration System
Common or Usual Name: Catheter, Thrombus Retriever
Classification: Class II, 21 CFR 870.1250 (Percutaneous Catheter)
Product Code and Review Panel:

Product Code	NRY
Review Panel	Neurology

III. PREDICATE AND REFERENCE DEVICES

Name of Predicate Device: Esperance Aspiration Catheter System
Name of Predicate Device Manufacturer: Wallaby Medical
510(k) number of Predicate Device: K211697

Name of Reference Device: Penumbra System ACE 68 Reperfusion Catheter
Name of Reference Device Manufacturer: Penumbra, Inc.
510(k) number of Reference Device: K161640

IV. DEVICE DESCRIPTION

Device Description:

The device is supplied as a kit consisting of a single Esperance® pHLO Aspiration Catheter, the Esperance Aspiration Tubing Set, and an introducer sheath, which combined comprise the Esperance® pHLO Aspiration System.

The Esperance® pHLO Aspiration Catheter is single lumen, flexible, variable stiffness composite catheter. A hub is attached to the proximal end, facilitating attachment of accessories, and the passage of devices into the inner lumen of the catheter, and connection to ancillary devices such as a vacuum source. A polymer sleeve is also attached to the hub and provides a gradual reduction in stiffness from the hub to the catheter shaft, in order to act as a strain relief.

A radiopaque marker is located approximately 0.6mm from the distal end of the catheter to allow visibility under fluoroscopy. Beyond the radiopaque marker comprises the soft atraumatic tip of the catheter. The following components: inner liner(s), braid, coil and polymer jackets are a part of the internal construction of the catheter. The distal 100cm of the catheter's external surface has a hydrophilic coating for increased lubricity during use. The Esperance pHLO Aspiration Catheter is offered with effective lengths of 125cm and 135cm with an outer diameter (OD) of 6F (0.083", 2.1mm) and an inner diameter (ID) of 0.071" (1.8mm).

The Esperance® pHLO Aspiration System is a non-active, surgically invasive device intended for short term use within the neurovasculature. The finished catheter is supplied sterile in a hoop, pouch and shelf carton configuration complete with an introducer sheath, aspiration tubing, and Directions for Use (DFU).

Environment of Use:

The Esperance® pHLO Aspiration System is solely intended for use by trained physicians in a healthcare facility/hospital.

V. INDICATIONS FOR USE

Table 1: Comparison of Indications for Use of the Esperance pHLO Aspiration System with the predicate and reference devices

Parameter	Predicate Device Esperance Aspiration Catheter System K211697	Reference Device Penumbra System ACE 68 Reperfusion Catheter K161640	Subject Device Esperance pHLO Aspiration System K251357
Indications for Use	The Esperance Aspiration Catheter with the Medela Dominant Flex Surgical Suction Pump and Wallaby Aspiration Tubing set is intended for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within 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-tPA) or who fail IV t-PA therapy are candidates for treatment.	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. As part of the Penumbra System, the Penumbra Sterile Aspiration Tubing is indicated to connect the Penumbra Reperfusion Catheters to the Penumbra Pump MAX.	As part of the Esperance pHLO Aspiration System, the Esperance pHLO Aspiration Catheter with a compatible aspiration pump and the Esperance Aspiration Tubing Set 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, basilar, and vertebral arteries) within 8 hours of symptom onset. Patients who are ineligible for thrombolytic drug therapy or who failed thrombolytic drug therapy are candidates for treatment.

The Indications for Use statement of the subject device is similar to both the predicate and reference device's intended use. All devices are intended to be used in the same segments of the nerovasculature and for the same treatment.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE AND REFERENCE DEVICES

Table 2: Comparison of technological characteristics of the Esperance pHLO Aspiration System, the predicate device Esperance Aspiration Catheter System, and reference device Penumbra System ACE 68 Reperfusion Catheter

Parameter	Predicate Device K211697	Reference Device K161640	Subject Device K251357
Device Name	Esperance Aspiration Catheter System	Penumbra System ACE 68 Reperfusion Catheter	Esperance pHLO Aspiration System
Model #	ASP6F131KIT ASP6F125KIT ASP6F115KIT ASP6F131 ASP6F125 ASP6F115	5MAXACE068KIT	PHLO-AC-71-135 PHLO-AC-71-125
510(k) Number	K211697	K161640	K251357
Product Classification	Class II	Class II	Class II
Product Code	NRY	NRY	NRY
Device Design/Materials	Nitinol braided shaft, Nitinol coil, polymeric exterior	Stainless Steel, Nitinol coil reinforcement, polymeric exterior	Stainless Steel braided shaft, Nitinol coil, polymeric exterior
Marker Band Material/ Radiopacity	Radiopaque C-cut Platinum/Iridium	Radiopaque Platinum/Iridium	Radiopaque C-cut Platinum/Iridium
Hub Material	Nylon	Grilamid	Polyamide
Coating	Hydrophilic coating Length: 60cm	Hydrophilic coating Length: 30cm	Hydrophilic coating Length: 100cm
Working Length	115cm 125cm 131cm	115cm 120cm 125cm 127cm 132 cm	125cm 135cm
Outer Diameter	0.084" max	0.084" max	0.083"
Inner Diameter	0.070" min	0.068" min	0.071"
Sterilization	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide
Shelf Life	12 months	8 months	12 months
Accessory Devices	Aspiration Tubing, Introducer Sheath, Shaping Mandrel	Aspiration Tubing, Peelable Sheath, Shaping Mandrel, RHV	Aspiration Tubing, Introducer Sheath
Packaging Components/Configuration	Device is stored within a HDPE Packaging Hoop sealed within a Tyvek to Nylon Pouch, which is then packaged in a product carton.	Device is stored within a polyethylene terephthalate, Polystyrene packaging tray, sealed within a Polyester/Polyethylene/Tyvek pouch, which is then packaged in a product carton.	Device is stored within a HDPE Packaging Hoop sealed within a Tyvek to Nylon Pouch, which is then packaged in a product carton.

VII. PERFORMANCE DATA

Biocompatibility

Biocompatibility testing for the Esperance pHLO Aspiration System was conducted based on International Organization for Standardization (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"". The aspiration tubing remains unchanged since prior clearance in K211697.

Table 3 below summarizes biocompatibility testing performed on Esperance pHLO Aspiration System.

Table 3: Biocompatibility Testing Results for Esperance pHLO Aspiration System

Test	Test Description	Conclusion
Esperance pHLO Aspiration Catheter Test Results		
Cytotoxicity ISO 10993-5	MTT- L929 Cytotoxicity Study	No cytotoxic effect.
Sensitization ISO 10993-10	ISO Guinea Pig Maximization Sensitization	No sensitization indicated.
Skin Irritation ISO 10993-10	ISO Intracutaneous Irritation	No sensitization indicated.
Systemic Toxicity ISO 10993-11	ISO Acute Systemic Toxicity	No acute systemic toxicity indicated.
Materials Mediated Pyrogenicity ISO 10993-11 USP <151>	ISO Materials Mediated Rabbit Pyrogen (GLP)	Esperance pHLO Aspiration Catheter is deemed non- pyrogenic.
Hemocompatibility ISO 10993-4	Hemolysis (ASTM method) Direct and Indirect Contact	Esperance pHLO Aspiration Catheter is deemed non-hemolytic.
	Partial Thromboplastin Time (PTT)	Esperance pHLO Aspiration Catheter is deemed comparable to predicate.
	Dog Thrombogenicity	Esperance pHLO Aspiration Catheter is deemed comparable to predicate.
	Platelet and Leukocyte Count	Esperance pHLO Aspiration Catheter is deemed comparable to predicate
Complement Activation Assay ISO 10993-4	Complement System Activation Assay SC5b-9 Assay	Esperance pHLO Aspiration Catheter is deemed a non-activator of the complement system.
Introducer Sheath		
Cytotoxicity ISO 10993-5	ISO MEM Elution	No cytotoxic effect.
Sensitization ISO 10993-10	Magnusson- Kligman Guinea Pig Maximization	No sensitization indicated.
Skin Irritation ISO 10993-23	Intracutaneous Reactivity	No sensitization indicated.
Systemic Toxicity **ISO 10993-11**	Acute Systemic Toxicity	No acute systemic toxicity indicated.

Materials Mediated Pyrogenicity ISO 10993-11 USP <151>	Material Mediated Pyrogenicity	Test articles are deemed non-pyrogenic.
Hemocompatibility ISO 10993-4	Hemolysis (ASTM method) Indirect Contact	Introducer sheath is deemed non-hemolytic.

Sterilization

The Esperance pHLO Aspiration System is sterilized by Ethylene Oxide gas. The sterilization cycle was verified to ensure a sterility assurance level (SAL) of 10^{-6}. Sterilization takes place in Rose, Trier, Germany.

The Esperance pHLO Aspiration System has been adopted into an existing validated cycle per EN ISO 11135:2014 and AAMI TIR28:2009.

Standards utilized with regards to Sterilization:
ISO 11135:2014 "Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices"

FDA Guidance Documents utilized with regards to Sterilization:

"Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labelled as Sterile" (2024)The sterilization cycle has been validated via the half cycle method.

Shelf-Life

Shelf-life conditioning has been completed and testing has been performed on devices subjected to the accelerated aging (AA) process to represent 1 year of aged units. Devices subjected to 1 year AA were bench tested as per Table 4 below, which ensures design and performance specification requirements were met after the one-year shelf-life that Esperance pHLO Aspiration System will have at commercialization. All tests conducted after accelerated aging met the acceptance criteria.

FDA Guidance Documents utilized with regards to Shelf Life:

"Coronary, Peripheral, and Neurovascular Guidewires – Performance Tests and Recommended Labeling" (2019)

"Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters - Class II Special Controls Guidance for Industry and FDA" (2010)

Non-Clinical Performance Data

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

PERFORMANCE TESTING - BENCH

A suite of performance testing on the bench was carried out on Esperance pHLO Aspiration System. The results of this testing demonstrated compliance to all the design attributes and that the device performs as intended. The results of these tests, in conjunction with the substantial equivalence claims as outlined in the premarket notification, demonstrate substantial equivalence to the cited predicate device. Table 4 below summarizes the tests and results.

Table 4: Summary of Bench Performance Testing

Test	Test Method Summary	Results
Manoeuvrability / Trackability	The catheter is tested for its ability to reach target site in an anatomical model.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended.
Trackability (Catheter Track Force)	The forces required to deliver the catheter to the target site are measured and compared to predicate device.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended. This is comparable with the predicate device, thus supporting substantial equivalence.
Pushability	The catheter is tested for its ability to reach a target site in an anatomical model without damage to the device.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended.
Simulated Use (Clot Retrieval)	The catheter was tested to demonstrate it can be safely and reliably prepared, delivered, and retracted as described in the instructions for use without damage to the device. The device system was tested to demonstrate is can retrieve synthetic clots from a 3D neurovascular model as described in the instructions for use. Ancillary device compatibility is verified.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended.

Test	Test Method Summary	Results
Aspiration Flow Rate	The device is connected to a vacuum pressure source and fluid is aspirated for a set duration and pressure to determine the flow rate.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended. This is comparable with the predicate device, thus supporting substantial equivalence.
Torque Strength	The catheter was evaluated for torque strength by rotating the test sample within an anatomical model. The catheter must exceed a specified minimum number of rotations.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended. This is comparable with the predicate device, thus supporting substantial equivalence.
Kink Resistance	The catheter is tested at different locations for its ability to bend to clinically relevant radii without kinking.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended. This is comparable with the predicate device, thus supporting substantial equivalence
Lumen Patency	The catheter is tested for its ability to maintain lumen patency during simulated use and under a specified vacuum pressure and duration.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended. This is comparable with the predicate device, thus supporting substantial equivalence.
Tip Stiffness	The distal soft portion of the catheter is deflected using a pin, and the maximum force required to deflect the catheter tip by a specified distance is measured.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended. The tip stiffness is similar or lower than the predicate device.
Tip Configuration	The catheter tip is inspected for smoothness.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended.
Flexural Fatigue	The catheters flexural fatigue is tested by simulated use through a clinically relevant neurovascular model as a specified number of insertions and withdrawals.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended.
Hydrophilic	The length of the hydrophilic coating is measured.	All samples met the acceptance criteria, confirming the

Test	Test Method Summary	Results
Coating Length		device meets requirements to ensure it performs as intended.
Hydrophilic Coating Lubricity	The catheter's hydrophilic coating lubricity is tested by applying a force to the coated section of the catheter. The friction force shall be equal to or below the specified maximum friction values.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended. This is comparable with the reference device, thus supporting substantial equivalence.
Hydrophilic Coating Durability	The catheter's hydrophilic coating durability is tested by applying a force to the coated section of the catheter. The coating durability shall be equal to or below the specified maximum durability values.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended.
Hydrophilic Coating Integrity	The coated length of device is inspected for defects post simulated use.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended.
Tensile Strength	Catheter sections are tensile tested to failure to verify a minimum specification is met.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended.
Inner Diameter	A calibrated pin of a specified diameter is passed through the inner lumen of the device.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended.
Chemical Compatibility	The catheter is inspected post exposure to saline and contrast media.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended.
Corrosion Resistance	The catheter is inspected post exposure to a saline solution for a specified period of time.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended.
Outer Diameter	The outer diameter of the catheter is measured.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended.

Test	Test Method Summary	Results
Catheter External Surface Finish	The catheter is inspected for pre-defined criteria.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended.
Freedom from Leakage at Rated Burst Pressure	The catheter is tested for its ability to withstand specified internal pressure without leakage.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended.
Static Burst Pressure	The catheter is tested for burst pressure under static conditions.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended.
Freedom from Leakage during Aspiration	The catheter is tested to ensure that there is no leakage within the catheter and tubing during aspiration.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended.
Vacuum Pressure	The vacuum pressure at the device tip is measured during pump activation and compared to the vacuum pressure generated at the aspiration pump.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended. This is comparable with the predicate device, thus supporting substantial equivalence.
Effective Length	The catheter's effective length is measured.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended.
Tip Length	The catheter's tip length is measured.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended.
Radio-Detectability	The image of the catheter is captured under fluoroscopy and compared with the predicate device.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended. This is comparable with the predicate device, thus

Test	Test Method Summary	Results
		supporting substantial equivalence.
Particulate Generation	The device is exposed to simulated use conditions. Effluent is collected during use, which is then analysed for particulates generated.	All samples met the acceptance criteria, confirming the device meets requirements to ensure it performs as intended. This is comparable with the predicate device, thus supporting substantial equivalence.

Standards utilized with regards to Bench Testing:
ISO 10555-1:2013/A1:2017 "Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements"
ISO 80369-20: 2015&LC:2015 "Small-bore connectors for liquids and gases in healthcare applications - Part 20: Common test methods"
ISO 80369-7:2021 "Small-bore connectors for liquids and gases in healthcare application - Part 7: Connectors for intravascular or hypodermic applications"
ISO 62366-1: 2015 + AC:2015 &A1 2020 "Medical Devices- Part 1: Application of Usability Engineering to Medical Devices"

FDA Guidance Documents utilized with regards to Bench Testing:
"Coronary, Peripheral, and Neurovascular Guidewires – Performance Tests and Recommended Labeling" (2019)
"Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters - Class II Special Controls Guidance for Industry and FDA" (2010)
"Applying Human Factors and Usability Engineering to Medical Devices" (2016)

Clinical Testing

Clinical testing was not performed on the Esperance pHLO Aspiration System as no human studies were deemed necessary to establish substantial equivalence.

Animal Testing

An animal study was not deemed necessary to support the substantial equivalence of the subject device to the predicate device. Bench testing was determined sufficient to support substantial equivalence.

VIII. CONCLUSIONS

Phenox Ltd. has demonstrated that the Esperance pHLO Aspiration System is substantially equivalent to the predicate Esperance Aspiration Catheter System (K211697). The subject device has the same intended use, similar technological characteristics, similar materials, and the same operating principle as the predicate device. The differences do not raise new questions of safety or effectiveness.

The subject device has been demonstrated to perform as intended through successful non-clinical performance testing.