May 7, 2026

Q'Apel Medical, Inc.
Jennifer Mateus
Vice President, Regulatory, Quality and Clinical Affairs
4245 Technology Drive
Fremont, California 94538

Re: K254276
Trade/Device Name: Lynx Aspiration Catheter System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NRY
Dated: December 29, 2025
Received: December 30, 2025

Dear Jennifer Mateus:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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
OHT5: Office of Neurological and
Physical Medicine 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)*
K254276

Device Name
Lynx™ Aspiration Catheter System

Indications for Use *(Describe)*
The Lynx Aspiration Catheter with the Aspiration Tubing and a compatible suction pump 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 fail thrombolytic drug therapy are candidates for treatment.

The Aspiration Tubing is indicated to connect the Lynx Aspiration Catheter to the compatible suction pump.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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
K254276
Lynx™ Aspiration Catheter System

Date Prepared: May 6, 2026

I. SUBMITTER

Q'Apel Medical, Inc.
4245 Technology Drive
Fremont, CA 94538 United States

Contact Person
Jennifer Mateus
Vice President, Regulatory, Quality and Clinical Affairs
4245 Technology Drive
Fremont, CA 94538 United States
408-896-4940
jmateus@qapelmedical.com

II. DEVICE

Name of Device:	Lynx™ Aspiration Catheter System
Common or Usual Name:	Catheter, Thrombus Retriever
Classification Regulation:	21 CFR § 870.1250
Regulation Name:	Percutaneous Catheter
Product Codes:	NRY
Regulatory Class:	II

III. PREDICATES

- Penumbra System (Reperfusion Catheter RED 72), K242104
- Penumbra System (Reperfusion Catheter RED 62), K203440
- Penumbra System (Reperfusion Catheter RED 43), K222808

IV. DEVICE DESCRIPTION

The Lynx™ Aspiration Catheter (Lynx) is intended for the removal of thrombus from the neurovasculature under aspiration when used in conjunction with the Aspiration Tubing and a commercially available compatible suction pump. The Lynx is a single-lumen, variable-stiffness catheter with a hydrophilic coating to minimize friction during navigation. The catheter features a radiopaque marker at the distal end for angiographic visualization and a luer hub at the proximal end for flushing and aspiration connections. The Lynx is introduced through a guide catheter or long sheath into the intracranial vasculature and navigated to the target occlusion with the aid of common interventional devices.

The Lynx is offered in various working lengths, nominal inner diameters (IDs) and outer diameters (ODs), and is designed for either individual or coaxial use to assist in accessing the target vasculature (aspiration is solely applied through the inner catheter when used coaxially).

The Lynx is provided sterile, non-pyrogenic, and is intended for single use only.

The Lynx is packaged with the following accessories: Rotating Hemostasis Valve (RHV), Aspiration Tubing with Flow Switch and Aspiration Tubing Extension, and Scale Card.

V. INDICATIONS FOR USE

The Lynx Aspiration Catheter with the Aspiration Tubing and a compatible suction pump 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 fail thrombolytic drug therapy are candidates for treatment.
The Aspiration Tubing is indicated to connect the Lynx Aspiration Catheter to the compatible suction pump.

VI. COMPARISION OF TECHNOLOGICAL CHARACTERISICS WITH PREDICATES

The Lynx and the predicate devices, Penumbra System with Reperfusion Catheters RED 72 (K242104), RED 62 (K203440) and RED 43 (K222808), share the same fundamental design and technological characteristics, similar materials, and sterilization method.

The following table compares key features of the subject and predicate devices.

Characteristic	**Subject Device Lynx™ Aspiration Catheter System**	**Predicate Device Penumbra System (Reperfusion Catheter RED 72) K242104**	**Predicate Device Penumbra System (Reperfusion Catheter RED 62) K203440**	**Predicate Device Penumbra System (Reperfusion Catheter RED 43) K222808**
Indications for Use	The Lynx Aspiration Catheter with the Aspiration Tubing and a compatible suction pump 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 fail thrombolytic drug therapy are candidates for treatment. The Aspiration Tubing is indicated to connect the Lynx Aspiration Catheter to the compatible suction pump.	Penumbra Reperfusion Catheters and Separators 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. Patients who are ineligible for thrombolytic drug therapy or who failed thrombolytic drug therapy are candidates for treatment. Penumbra 3D Revascularization Device As part of the Penumbra	Penumbra Reperfusion Catheters and Separators 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. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.	Penumbra Reperfusion Catheters and Separators 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. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.

Characteristic	Subject Device Lynx™ Aspiration Catheter System	Predicate Device Penumbra System (Reperfusion Catheter RED 72) K242104	Predicate Device Penumbra System (Reperfusion Catheter RED 62) K203440	Predicate Device Penumbra System (Reperfusion Catheter RED 43) K222808
		System, the Penumbra 3D Revascularization Device 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) within 8 hours of symptom onset. Patients who are ineligible for thrombolytic drug therapy or who failed thrombolytic drug therapy are candidates for treatment. Penumbra Aspiration Tubing As part of the Penumbra System, the Penumbra Sterile Aspiration Tubing is indicated to connect the Penumbra Reperfusion Catheters to the Penumbra Aspiration Pump. Penumbra Aspiration Pump The Penumbra Aspiration Pump is indicated as a vacuum source for Penumbra Aspiration Systems.	Penumbra 3D Revascularization Device As part of the Penumbra System, the Penumbra 3D Revascularization Device 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) within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment. Penumbra Aspiration Tubing As part of the Penumbra System, the Penumbra Sterile Aspiration Tubing is indicated to connect the Penumbra Reperfusion Catheters to the Penumbra Aspiration Pump. Penumbra Aspiration Pump The Penumbra Aspiration Pump is indicated as a vacuum source for Penumbra Aspiration Systems.	Penumbra 3D Revascularization Device As part of the Penumbra System, the Penumbra 3D Revascularization Device 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) within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment. Penumbra Aspiration Tubing As part of the Penumbra System, the Penumbra Sterile Aspiration Tubing is indicated to connect the Penumbra Reperfusion Catheters to the Penumbra Aspiration Pump. Penumbra Aspiration Pump The Penumbra Aspiration Pump is indicated as a vacuum source for Penumbra Aspirati on Systems.
Product Code	NRY	NRY	NRY	NRY
Classification	Class II	Class II	Class II	Class II

Characteristic	Subject Device Lynx™ Aspiration Catheter System	Predicate Device Penumbra System (Reperfusion Catheter RED 72) K242104	Predicate Device Penumbra System (Reperfusion Catheter RED 62) K203440	Predicate Device Penumbra System (Reperfusion Catheter RED 43) K222808
Materials	Stainless Steel laser cut tube LCT, Nitinol LCT, Nylon, Pebax, polytetrafluoroethylene (PTFE), Polycarbonate, Polyurethane (NEUsoft), 25 Denier Vectran Fiber (072 Aspiration Catheter only)	Stainless Steel, PTFE, Polyurethane, Polyether Block Amide, Nylon 12, Nitinol, Platinum/Iridium	Stainless Steel, PTFE, Polyurethane, Polyether Block Amide, Nylon 12, Nitinol, Platinum/Iridium	Stainless Steel, PTFE, Polyurethane, Polyether Block Amide, Nylon 12, Nitinol, Platinum/Iridium
Aspiration Catheter Design	Single lumen, variable stiffness	Single lumen, variable stiffness	Single lumen, variable stiffness	Single lumen, variable stiffness
Distal Radiopaque Marker	Yes	Yes	Yes	Yes
Marker Band	Platinum (90%)/Iridium (10%)	Platinum (90%) /Iridium (10%)	Platinum (90%) /Iridium (10%)	Platinum (90%) /Iridium (10%)
ID Band Color	Proflex [green]	Polyolefin, PET black [white foil]	Polyolefin, PET black [white text]	Polyolefin, PET black [white text]
Inner Diameter	072: 0.072 in. 058: 0.058 in. 044: 0.044 in.	RED 72: 0.072 in	RED 62: 0.062 in.	RED 43: 0.043 in.
Outer Diameter	072: 0.084 in 058: 0.070 in 044: 0.056 in	RED 72: 0.085 in	RED 62: 0.076 in.	RED 43: Proximal OD 0.060 in. Distal OD 0.056 in.
Effective Length	072: 132 cm 058: 138 cm, 149 cm 044: 145 cm, 160 cm	RED 72: 115cm, 120cm, 125cm, 127cm, 132 cm	RED 62: 115, 120, 125, 127,132, 138, 160 cm	RED 43: 115, 120, 125, 127, 132, 136, 138, 145, 150, 153, 155, 160, 162, 167 cm
Hydrophilic Coating	Hydrophilic (proprietary)	Hydrophilic (proprietary)	Hydrophilic (proprietary)	Hydrophilic (proprietary)
Hydrophilic Coating Length	072 and 058: 30 cm 044: 50 cm	RED 72: 30 cm	RED 62: 30 cm	RED 43: 60 cm
Tip Shapes Offered	Straight	Shapeable	Shapeable	Shapeable
Accessories Supplied	RHV, Aspiration Tubing with Flow Switch and Aspiration Tubing Extension, Scale Card	RHV, Peelable Sheath, Shaping Mandrel, SENDit (optional), Aspiration Tubing with Flow Switch (integral to the tubing)	RHV, Peelable Sheath, Shaping Mandrel, Aspiration Tubing with Flow Switch (integral to the tubing)	RHV, Peelable Sheath, Shaping Mandrel, Aspiration Tubing with Flow Switch (integral to the tubing)
Sterile Aspiration Tubing	Yes	Yes	Yes	Yes
Aspiration Tubing Inner Diameter	0.110 in.	0.110 in.	0.110 in.	0.110 in.
Aspiration Tubing Effective Length	98 in.	112 in.	112 in.	112 in.
Aspiration Pump Vacuum Pressures	Between -20 inHg and -29 inHg	Between -20 inHg and -29 inHg	Between -20 inHg and -29 inHg	Between -20 inHg and -29 inHg
Packaging Materials	Pouch: Tyvek (polyethylene), Mylar (Polyester) Backer Card: PETG (Polyethylene	Pouch: Polyester / Polyethylene/Tyvek Tray: Polystyrene Carton: SBS Paperboard	Pouch: Polyester / Polyethylene/ Tyvek Tray: Polystyrene Carton: SBS Paperboard	Pouch: Polyester /Polyethylene/ Tyvek Tray: Polystyrene Carton: SBS Paperboard

Characteristic	Subject Device Lynx™ Aspiration Catheter System	Predicate Device Penumbra System (Reperfusion Catheter RED 72) K242104	Predicate Device Penumbra System (Reperfusion Catheter RED 62) K203440	Predicate Device Penumbra System (Reperfusion Catheter RED 43) K222808
	terephthalate glycol) Carton: SBS Paperboard			
Condition Supplied	Sterile	Sterile	Sterile	Sterile
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide

VII. PERFORMANCE DATA

The results of verification and validation testing conducted on the Lynx demonstrate that the device performs as intended and is substantially equivalent to the predicate. The following performance data were provided in support of the substantial equivalence determination:

Test Name	Objective	Result
Dimensional/Visual Test	To demonstrate the device meets all dimensional and visual product specifications.	The device met the acceptance criteria.
Friction Test (Coating Lubricity)	To evaluate the catheter coating lubricity (frictional forces).	The device met the acceptance criteria.
Radiopacity Test	To demonstrate that the catheter's distal marker band is clearly visible under typical fluoroscopic imaging conditions.	The device met the acceptance criteria.
Simulated Use Test	To demonstrate the device can remove clots using a clinically relevant benchtop model.	The device performs as intended under simulated use conditions.
Delivery and Retrieval Test	To demonstrate the catheter meets delivery and retrieval force specifications.	The device met the acceptance criteria.
Lumen Collapse	To demonstrate the device lumen (catheter and aspiration tubing) does not collapse under aspiration pressures expected in clinical use.	The device met the acceptance criteria.
Particulate and Coating Integrity Test	To demonstrate the quantity and size of particles generated during simulated use (including multiple deployment cycles) are comparable to the predicates and reference devices. To demonstrate the catheter hydrophilic coating has sufficient integrity after simulated use.	The device met the acceptance criteria.
Hub Liquid Leakage and Air Leakage Tests	To demonstrate the device (catheter) has no liquid leakage or air leakage per test methods described in ISO 10555-1.	The device met the acceptance criteria.
Functionality and Leakage Test (Aspiration Tubing)	To demonstrate functionality of the flow switch to control fluid flow of aspiration tubing. To demonstrate resistance of the aspiration tubing to leakage under vacuum.	The device met the acceptance criteria.
Tensile Test	To demonstrate the device (catheter, aspiration tubing) has adequate tensile strength including all bonds and joints.	The device met the acceptance criteria.
Elongation Test	To demonstrate the device achieves adequate elongation before breaking under tensile test conditions.	The device met the acceptance criteria.
Corrosion Resistance Test	To demonstrate that the catheter has no visual evidence of corrosion when tested per methods described in ISO 10555-1.	The device met the acceptance criteria.
Torque Strength Test	To demonstrate the catheter has sufficient torque strength in the simulated use model.	The device met the acceptance criteria.
Burst Pressure Test	To demonstrate the catheter can withstand sufficient pressure for clinical use.	The device met the acceptance criteria.
Distal Tip Stiffness Test	To demonstrate the catheter distal tip stiffness is comparable to the predicate.	The device met the acceptance criteria.
Kink Resistance Test	To demonstrate the catheter is resistant to kinking.	The device met the acceptance criteria.
Luer Hub Tests	To demonstrate conformance with ISO 80369-7 for small bore connectors for intravascular use.	The device met the acceptance criteria.
Simulated Use	To demonstrate the device usability in removing	The device performs as intended under

Test Name	Objective	Result
Physician Usability Test	clots using a clinically relevant benchtop model, with comparison to the predicate.	simulated use conditions.
Shelf Life	To demonstrate that the device performance and packaging integrity is maintained over the proposed shelf-life (6 months).	The device met the acceptance criteria.
Packaging Validation	To demonstrate the packaging of the device meets all product specifications.	The device met the acceptance criteria.

VIII. BIOCOMPATIBILITY

The subject Lynx Aspiration Catheter is categorized as limited exposure (≤ 24 hours), externally communicating device with circulating blood contact in accordance with ISO 10993-1. The Aspiration Tubing and RHV are categorized as limited exposure (≤ 24 hours), externally communicating devices with indirect contact with circulating blood. The following testing supports biocompatibility and substantial equivalence of the subject device.

Test Name	Results	Conclusion
Cytotoxicity: MEM Elution	Non-cytotoxic	Pass
Sensitization: Magnusson-Kligman Method	Non-sensitizing	Pass
Irritation: Intracutaneous Reactivity	Non-irritant	Pass
Acute Systemic Toxicity: Acute Systemic Injection	Non-toxic	Pass
Systemic Toxicity: Material Mediated Pyrogenicity	Non-pyrogenic	Pass
Hemocompatibility: Hemolysis - Direct and Indirect	Non-hemolytic	Pass
Hemocompatibility: Platelet and Leukocyte Count	Comparable to the predicate	Pass
Hemocompatibility: Complement Activation	Non-activator of the complement system	Pass
Hemocompatibility: In-vivo Thrombogenicity	Comparable to the predicate	Pass
Hemocompatibility: Partial Thromboplastin Time (PTT)	Comparable to the predicate	Pass

IX. STERILITY

The subject Lynx is sterilized with ethylene oxide (EO). The sterilization process has been validated in accordance with ISO 11135:2014 to achieve a sterility assurance level (SAL) of $1x\ 10^{-6}$. EO and Ethylene Chlorohydrin (ECH) residuals were below the limits specified in ISO 10993-7:2008. Bacterial endotoxin levels were below the level of 2.15 endotoxin units (EU)/device. Both baseline and accelerated aged shelf-life testing were conducted demonstrating the device and packaging will perform as intended to support the proposed 6-month shelf-life.

X. ANIMAL STUDY

A Good Laboratory Practices (GLP) animal study was conducted to evaluate the safety and performance of the Lynx Aspiration Catheter (072 model) System in comparison to the predicate Penumbra System (Reperfusion Catheter RED 72) in a porcine model. Six animals were evaluated at 3-day and 30-day timepoints. The complete test system (catheter, aspiration tubing, pump) was compared to the complete control system. Study procedures included aspiration of soft and firm experimental clots from ascending pharyngeal arteries and renal artery branches, and wedge assessments under maximum vacuum conditions in lingual arteries. Three passes were performed per vessel. Vessels were evaluated via angiography, gross necropsy, and histopathology by a board-certified veterinary pathologist. Performance was comparable between test and control devices. Histopathology revealed minimal to mild vascular injury at 3 days with appropriate healing by 30 days. The pathologist concluded that the test and control devices demonstrated comparable safety profiles with no evidence of excess or unexpected pathology in the test group.

XI. CLINICAL

Clinical testing was not deemed necessary to support the substantial equivalence of the Lynx Aspiration Catheter System.

XII. CONCLUSION

The subject device, the Lynx Aspiration Catheter System is substantially equivalent to the predicate devices considering the same intended use, similar technological characteristics, and results of the non-clinical testing. The Lynx Aspiration Catheter System incorporates similar design features and procedural steps and the differences do not raise any new or different questions of safety or effectiveness when compared to the predicate devices. Safety and performance testing demonstrates that the Lynx Aspiration Catheter System performs as intended.