August 25, 2023

Q'Apel Medical, Inc.
Kim Ky
Manager, Regulatory Affairs
4245 Technology Drive
Fremont, California 94538

Re: K222786
Trade/Device Name: 072 Aspiration System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NRY
Dated: August 17, 2023
Received: August 17, 2023

Dear Kim Ky:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. 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 located 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.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222786

Device Name
072 Aspiration System

Indications for Use *(Describe)*

072 Aspiration Catheter:
As part of the 072 Aspiration System, the 072 Aspiration Catheter with 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 intravenous tissue plasminogen activator (IV t-PA) or who failed IV t-PA therapy are candidates for treatment.

Aspiration Tubing:
As part of the 072 Aspiration System, the Aspiration Tubing is intended to connect the 072 Aspiration Catheter to a 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
As required by 21 CFR 807.92

Applicant:
Submitter's Name: Q'Apel Medical, Inc.
Address: 4245 Technology Drive
Fremont, CA 94538

Telephone: 510-738-6255

Contact Person: Kim Ky
Title: Manager, Regulatory Affairs
Telephone: 510-828-4757

Date Prepared: August 25, 2023

Device Name /Common name: 072 Aspiration System

Classification: Class II

Product Code(s): NRY

Regulation Number(s): 21 CFR 870.1250

Classification Name: Percutaneous, Catheter

Predicate Device: Penumbra System® [JET™ 7 Reperfusion Catheter with MAX Delivery Device (JET™ 7MAX)] (K191946)

Reference Devices: CERENOVUS Large Bore Catheter; CERENOVUS Aspiration Tubing Set (K193380)
Penumbra System® (Reperfusion Catheter RED™ 72) (K211654)

Indications for Use:
072 Aspiration Catheter

As part of the 072 Aspiration System, the 072 Aspiration Catheter with 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 intravenous tissue plasminogen activator (IV t-PA) or who failed IV t-PA therapy are candidates for treatment.

Aspiration Tubing

As part of the 072 Aspiration System, the Aspiration Tubing is intended to connect the 072 Aspiration Catheter to a compatible suction pump.

Device Description:

The 072 Aspiration Catheter is a single lumen, variable stiffness catheter. The catheter has a hydrophilic coating to reduce friction during use. The catheter includes radiopaque markers on the distal end for angiographic visualization and a Luer hub on the proximal end allowing attachments for flushing and aspiration. The Delivery Tool is an optional accessory for use with the 072 Aspiration Catheter and should be removed prior to aspiration. The 072 Aspiration Catheter, Delivery Tool, Rotating Hemostasis Valve, and Flow Switch are included in the package. The Aspiration Tubing is provided in a separate package.

For the aspiration source, the 072 Aspiration Catheter is used in conjunction with a compatible suction pump with prespecified performance parameters that is connected using the Aspiration Tubing.

Comparison of Technological characteristics with the Predicate Device:

Q'Apel Medical, Inc. has demonstrated that the 072 Aspiration System is substantially equivalent to the predicate device, Penumbra System® [JET™ 7 Reperfusion Catheter with MAX Delivery Device (JET™ 7MAX)] cleared under K191946, based on the same or similar materials, similar design, and the same fundamental operating principles. A comparison of the subject device with the predicate and reference devices is summarized in the table below.

Comparison of the Subject, Predicate, and Reference Devices					
Feature	**Subject Device (K222786)**	**Predicate Device (K191946)**	**Reference Device 1 (K193380)**	**Reference Device 2 (K211654)**	**Rationale for difference (if applicable)**
Device Name	072 Aspiration System	Penumbra System (JET 7MAX)	CERENOVUS Large Bore Catheter; CERENOVUS Aspiration Tubing Set	Penumbra System (Reperfusion Catheter RED 72)	N/A
510(k) Number	K222786	K191946	K193380	K211654	N/A
Classification	Class II	Class II	Class II	Class II	Same
Product Code	NRY	NRY	NRY	NRY	Same
Classification Name	21CFR 870.1250	21CFR 870.1250	21 CFR 870.1250	21 CFR 870.1250	Same

Indications for Use	072 Aspiration Catheter As part of the 072 Aspiration System, the 072 Aspiration Catheter with 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 intravenous tissue plasminogen activator (IV t-PA) or who failed IV t-PA therapy are candidates for treatment. Aspiration Tubing As part of the 072 Aspiration System, the Aspiration Tubing is intended to connect the 072 Aspiration Catheter to a 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 intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment. 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	The CERENOVUS Large Bore Catheter, with the CERENOVUS Aspiration Tubing Set and NOUVAG Vacuson 60 aspiration pump (or equivalent aspiration 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 intravenous tissue plasminogen activator (IV t-PA) or who failed IV t-PA are candidates for treatment. The CERENOVUS Aspiration Tubing Set is intended to connect the CERENOVUS Large Bore Catheter to the canister of the NOUVAG Vacuson 60 Aspiration 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 intravenous tissue plasminogen activator (IV t-PA) or who fail IV tPA therapy are candidates for treatment. 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	Similar, the differences do not raise new questions regarding safety and effectiveness.

		therapy are candidates for treatment. <u>Penumbra Aspiration Tubing</u> As part of the Penumbra System, the Penumbra Sterile Aspiration Tubing is indicated to connect the Penumbra Reperfusion Catheters to the Penumbra Aspiration Pump. <u>Penumbra Aspiration Pump</u> The Penumbra Aspiration Pump is indicated as a vacuum source for Penumbra Aspiration Systems.	(or equivalent vacuum pump) and to allow the user to control the fluid flow.	onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment. <u>Penumbra Aspiration Tubing</u> As part of the Penumbra System, the Penumbra Sterile Aspiration Tubing is indicated to connect the Penumbra Reperfusion Catheters to the Penumbra Aspiration Pump. <u>Penumbra Aspiration Pump</u> The Penumbra Aspiration Pump is indicated as a vacuum source for Penumbra Aspiration Systems.	

Comparison of the Subject, Predicate, and Reference Devices					
Feature	**Subject Device (K222786)**	**Predicate Device (K191946)**	**Reference Device 1 (K193380)**	**Reference Device 2 (K211654)**	**Rationale for difference (if applicable)**
Aspiration Catheter	072 Aspiration Catheter	Penumbra JET™ 7	CERENOVUS Large Bore Catheter	Reperfusion Catheter RED 72	N/A
Length	132 cm	115, 120, 125, 127, 132 cm	125-135 cm	115, 120, 125, 127, 132 cm	Same
ID	0.072”	0.072” Min	0.071”	0.072”	Same as K191946 and K211654
Distal OD	0.0855”	0.085” Max	0.081”	0.085”	Same as K191946 and K211654
Proximal OD	0.0855”	0.085” Max	0.0825”	0.085”	Same as K191946 and K211654
Catheter Coating	Hydrophilic	Hydrophilic (proprietary)	Hydrophilic	Hydrophilic (proprietary)	Same
Tip Configuration	Straight	Straight	Non-shapeable tip	Straight	Same as K191946 and K211654
Coating Length	28cm +/- 4cm	30 cm	30 cm	30 cm	Similar, the differences do not raise new questions regarding safety and effectiveness.
Materials:					
Hub	Polycarbonate	Grilamid (TR55-LX)	Polyamide (Nylon)	Grilamid (TR55-LX)	Similar, the differences do not raise new questions regarding safety and effectiveness.
Liner	PTFE Liner	PTFE	PTFE Liner	PTFE Liner	Same

Catheter Shaft					
Extrusions	Nylon	Polyurethane	Pebax	Polyurethane	Similar, the differences do not raise new questions of safety and effectiveness.
	Pebax	Polyether Block Amide	Urethane	Polyether Block Amide	
	Polyurethane	Nylon 12	Nylon	Nylon 12	
Marker Band	Metal Platinum (90%) / Iridium (10%), Tantalum	Platinum (90%) /Iridium (10%)	Metal Platinum (90%) / Iridium (10%)	Platinum (90%) /Iridium (10%)	Similar, the differences do not raise new questions of safety and effectiveness.
Reinforced Shaft	Stainless Steel (SS), Coil	NiTi wire, SS wire	Stainless Steel, Nitinol, braid	NiTi wire, SS wire	Similar, the differences do not raise new questions of safety and effectiveness.
Strain Relief	Polyolefin	Polyolefin	Polyamide	Polyolefin	Same as K191946 and K211654
Accessories					
Peelable Sheath	N/A	PTFE	N/A	PTFE	N/A
Hemostasis Valve	Silicone O-ring, Polycarbonate, EPDM	Polycarbonate, silicone O-ring	Hemostasis Valve with Side Port Extension Tubing	Polycarbonate, silicone O-ring	Similar to K191946, differences do not raise new questions of safety and effectiveness.
Flow Switch	Silicone, Polycarbonate, Acetal, ABS	N/A	N/A	N/A	The difference does not raise new questions of safety and effectiveness.
Shaping Mandrel	N/A	Stainless Steel	N/A	Stainless Steel	N/A

Delivery Tool	**Materials:** Pebax, Tecoflex 93A, Tungsten 75% Filler **Dimensions:** ID: 0.026 in OD: 0.042 in Extension Length: 10 cm	**Materials:** Nylon 12, Copolyester, Polyolefin, Polyurethane, Polyether Block Amide, PTFE, Platinum/Tungsten, Hydrophilic Coating **Dimensions:** ID: 0.018 in OD: 0.071 in Extension Length: 1.5 cm	N/A	N/A	Similar, the differences do not raise new questions of safety and effectiveness.
Aspiration Tubing	**Dimensions:** ID: 0.110 in Tubing Length: 95 in	**Dimensions:** Tubing ID: 0.110 in ± 0.005 in Tubing Length: 112.0 in ± 7.0 in	**Dimensions:** ID: 0.110 in Tubing Length: 112 in	**Dimensions:** Tubing ID: 0.110 in ± 0.005 in Tubing Length: 112.0 in ± 7.0 in	Similar, the differences do not raise new questions of safety and effectiveness.
Flow Control Mechanism	Flow Control Switch	Flow Control Switch	Flow Control Switch	Flow Control Switch	Same as K191946, K193380, K211654
Packaging Material					
Pouch	Tyvek (polyethylene), Mylar (Polyester)	Polyester / Polyethylene/Tyvek	Polyethylene Hoop and Mounting Card, Pouch, Carton	Polyester / Polyethylene/Tyvek	Similar to K191946, the differences do not raise new questions of safety and effectiveness.
Packaging Tray (Kit Configuration)	PETG (Polyethylene terephthalate glycol)	Polyethylene terephthalate, Polystyrene		Polyethylene terephthalate, Polystyrene	
Display Carton	SBS Paperboard,	SBS Paperboard		SBS Paperboard	
Kit Packaging Configuration	Tray/Retainer/Lid /Accessory Pouch/Pouch/Box	Tray/Retainer/Lid/ Aspiration Tubing/Accessory Pouch/Pouch/Box		Tray/Retainer/Lid/ Aspiration Tubing/Accessory Pouch/Pouch/Box	
Shelf Life	6 months	36 months	1 year	36 months	The differences do not raise new questions of safety and effectiveness.
Sterilization Method	Ethylene oxide	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide	Same
Sterility Assurance Level (SAL)	10^{-6}	10^{-6}	10^{-6}	10^{-6}	Same

Performance Testing – Bench:

The necessary testing was identified based on design, risk analysis, and the intended use of the 072 Aspiration System to verify the device performs as intended and to demonstrate that it is substantially equivalent to the predicate device. The following performance data have been provided, supporting the substantial equivalence determination. All testing was conducted per Q'Apel Medical, Inc. Design Control procedures. The bench testing included the following tests:

Test	Test Summary	Result
Visual Surface Requirement	Confirm that the device meets the visual surface requirements.	Pass All samples met the predetermined acceptance criteria
Packaging Visual Inspection	Confirm that the packaging meets the visual inspection.	Pass All samples met the predetermined acceptance criteria
Dimensional/Visual Inspection	Device dimensions were measured to confirm conformance to the specifications.	Pass All samples met the predetermined acceptance criteria
Liquid Leakage Under Pressure	Verify that the catheter joint strength meets the freedom from leakage (liquid leakage during pressurization) requirements of ISO 10555-1:2013, Annex C.	Pass All samples met the predetermined acceptance criteria
Hub Aspiration Air Leakage	Confirm that the device passes the hub aspiration air leakage test of ISO 10555-1:2013, Annex D.	Pass All samples met the predetermined acceptance criteria
Simulated Use	Simulated use testing with accessories in an anatomical model which simulated the tortuosity of the neurovasculature. Devices were delivered through the tortuous model to evaluate effectiveness of the device at retrieval of soft and firm clots and mechanical integrity after multiple passes. Testing performed with reference device (K211564) for comparison.	Pass All samples met the predetermined acceptance criteria

Test	Test Summary	Result
Flex Fatigue	Meets minimum value per specification for multiple passes in the simulated use model.	Pass All samples met the predetermined acceptance criteria
Track and Advance Force	Test specimens were tested for track and advance force.	Pass All samples met the predetermined acceptance criteria
Tip Deflection	Test specimens were tested for tip deflection forces and compared to predicate catheters.	Pass All samples met the predetermined acceptance criteria
Torque	Determine the number of revolutions to failure of the Catheter in simulated anatomy.	Pass All samples met the predetermined acceptance criteria
Tip Elongation and Compression	Test specimens were tested for tip elongation and compression.	Pass All samples met the predetermined acceptance criteria
Peak Tensile	The tensile strength of the catheter sections and bonds was tested after simulated use.	Pass All samples met the predetermined acceptance criteria
Particulates, Coating Integrity	The integrity of the hydrophilic coating was evaluated after multiple insertion and withdrawal cycles. Particulates were measured during simulated use and compared to the reference device.	Pass All samples met the predetermined acceptance criteria
Flow Rate	Determine the flow rate through a catheter, based on ISO 10555-1, Annex E.	Pass All samples met the predetermined acceptance criteria
Aspiration Flow Rate	Determine the aspiration flow rate through the aspiration catheter when the catheter is connected to a constant vacuum source.	Pass All samples met the predetermined acceptance criteria
Kink Resistance	Test specimen segments were formed into a defined bend diameter to evaluate kink resistance.	Pass All samples met the predetermined acceptance criteria

Test	Test Summary	Result
Corrosion Resistance	No visible corrosion immediately after Corrosion Testing procedure based on ISO 10555-1, Annex A.	Pass All samples met the predetermined acceptance criteria
Radiopacity	The marker band is fluoroscopically visible.	Pass All samples met the predetermined acceptance criteria
Burst Pressure-Static	Tested per ISO 10555-1:2013, Annex F. Testing conducted after simulated use.	Pass All samples met the predetermined acceptance criteria
Burst Pressure-Dynamic	Minimum value per specification.	Pass All samples met the predetermined acceptance criteria
Connectors for Intravascular or Hypodermic Applications	Hubs were tested per ISO 80369-7.	Pass All samples met the predetermined acceptance criteria
Lumen Collapse	Aspiration Catheter samples were tested for lumen patency under maximum applied vacuum pressures.	Pass All samples met the predetermined acceptance criteria
Manual Syringe Injection Peak Pressure (psi)	Measure peak pressure during manual injection of contrast media with a syringe.	Pass All samples met the predetermined acceptance criteria

Q'Apel also confirmed that the Aspiration Tubing meets all design and performance requirements through the following bench testing:

Test	Test Summary	Result
Dimensional/Visual Inspection	Confirm that the Aspiration Tubing meets all dimensional and visual specifications.	Pass All samples met the predetermined acceptance criteria
Tensile Strength	Confirm that the Aspiration Tubing meets the existing tensile strength specifications.	Pass All samples met the predetermined acceptance criteria
Simulated Use Test	Confirm that the Aspiration Tubing passes testing specified in the simulated use test protocol.	Pass All samples met the predetermined acceptance criteria

Aspiration Tubing Resistance to Collapse and Leakage at Maximum Aspiration Pressures	Confirm that the Aspiration Tubing resistance to collapse at maximum aspiration pressure testing is as specified in the test protocol. Confirm that the Aspiration Tubing does not show signs of leakage at maximum aspiration pressure.	Pass All samples met the predetermined acceptance criteria
Flow Switch Functionality Testing	The Flow Control Switch completely and immediately stops fluid flow after a specified number of ON/OFF cycles.	Pass All samples met the predetermined acceptance criteria

Performance Testing – Animal:

An animal study was conducted to evaluate the safety, effectiveness, and usability of the 072 Aspiration System in comparison to cleared control devices, the CERENOVUS Large Bore Catheter (K193380) and the Penumbra System (Reperfusion Catheter RED 72) (K211654), in a porcine model according to Good Laboratory Practices (GLP) per 21 CFR Part 58. Sub-chronic and chronic time points were assessed. The study included aspiration of experimental clots and a worst-case wedge assessment. Clot aspiration and wedge assessment were comparable between the test and control catheters, and both were shown to be safe in porcine vessels via angiography and vessel histology.

Performance Data – Clinical:

No clinical study was conducted as bench and animal testing was determined sufficient for verification and validation purposes and to support the substantial equivalence of the 072 Aspiration System.

Sterilization:

The 072 Aspiration System, which includes the Aspiration Tubing, is sterilized using a validated 100% Ethylene Oxide sterilization process to ensure sterility assurance level (SAL) of 10^{-6} in accordance with AAMI TIR 28:2016 "*Product Adoption and Process Equivalence for Ethylene Oxide Sterilization*" and per the requirements of 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.*" The 072 Aspiration System, accessories, and Aspiration Tubing are for single use only.

Shelf-Life Testing:

The 072 Aspiration System, which includes the Aspiration Tubing, has a shelf life of six months based on the successful completion of stability testing. Shelf-life testing was performed using standard test methods and acceptance criteria. All samples were exposed to standard transportation conditioning and distribution before aging. Results of testing on the subject device met the established acceptance criteria.

Biocompatibility Testing:

The 072 Aspiration System was assessed for biocompatibility in accordance with ISO 10993-1, "*Biological Evaluation of Medical Devices – Part 1: Evaluation of Testing within a Risk Management Process,*" and the FDA Guidance for Industry and FDA Staff, "*Use of International Standard ISO 10993-1, "Biological evaluation of medical devices -Part 1: Evaluation and testing within a risk management process"*," (issued September 4, 2020).

The 072 Aspiration Catheter and the Delivery Tool are considered externally communicating medical devices with direct contact with circulating blood for a limited (≤ 24 hours) duration.

The Rotating Hemostasis Valve (RHV), Flow Switch, and Hub are considered external communicating devices contacting blood indirectly for a limited (≤ 24 hours) duration.

The Aspiration Tubing is considered to have contact with intact skin for a limited (≤ 24 hours) duration.

Biocompatibility testing on the 072 Aspiration System (072 Aspiration Catheter and Delivery Tool) included:

Test Name	Acceptance Criteria	Conclusion
Cytotoxicity – MEM Elution ISO 10993-5:2009	The achievement of a numerical grade greater than 2 is considered a cytotoxic effect.	Non-cytotoxic
Sensitization Magnusson- Kligman Method ISO 10993-10:2010	Magnusson and Kligman grades of 1 or greater in the test group generally indicate sensitization, provided grades of less than 1 are seen in control animals. If grades of 1 or greater are noted in control animals, then the reactions of test animals which exceed the most severe reaction in control animals are presumed to be due to sensitization.	Non-sensitizing
Irritation: Intracutaneous Reactivity ISO 10993-23:2021	The requirements of the test were met if the final test article score was ≤ 1.0.	Non-irritating

Acute Systemic Toxicity ISO 10993-11:2017	If using five animals per group, the test article meets the requirement of the test if none of the following circumstances occur: 1. Two or more animals from the test group die. 2. Animal behavior, such as convulsions or prostration, occurs in two or more animals from the test group. 3. A final (end of study) body weight loss > 10% occurs in three or more animals from the test group.	Non-toxic
Material Mediated Pyrogenicity ISO 10993-11:2017, USP 151	The requirements of the test were met if no rabbit showed an individual rise in temperature of 0.5 °C or more above its respective baseline temperature throughout the duration of the test.	Non-pyrogenic
ASTM Hemolysis- Direct (direct blood contact components only) ISO 10993-4: 2017 ASTM F756-17	The positive control's mean hemolytic index above the negative control must be ≥ 5% for the direct method. The negative control must display a mean hemolytic index of < 2 % for the direct method.	Non-hemolytic for the Direct Method
ASTM Hemolysis- Indirect (indirect blood contact components only) ISO 10993-4: 2017 ASTM F756-17	The positive control's mean hemolytic index above the negative control must be ≥ 5% for the indirect method. The negative control must display a mean hemolytic index of < 2 % for the indirect method.	Non-hemolytic for the Indirect Method
Hemocompatibility- Complement Activation (direct blood contact components only) ISO 10993-4: 2017	The negative control (HDPE) concentration must not be significantly higher when compared to the NHS at 37 °C concentration or the final concentration must fall within ± 1 standard deviation of the mean in the test facility historical range for HDPE. The positive reference control (Latex) concentration must be statistically significant when compared to the NHS at 37 °C concentration or the final concentration must fall within ± 1 standard deviation of the mean in the test facility historical range for Latex.	Non-activator of the Complement System

Thrombogenicity ISO 10993-4: 2017	The thrombogenic potential of a blood-contacting medical device must be comparable to a predicate device.	Non-thrombogenic

Biocompatibility testing on the Aspiration Tubing included:

Test Name	Acceptance Criteria	Conclusion
Cytotoxicity – MEM Elution ISO 10993-5:2009	The achievement of a numerical grade greater than 2 is considered a cytotoxic effect.	Non-cytotoxic
Sensitization Magnusson-Kligman Method ISO 10993-10:2010	Test group shall yield Grade < 1 score on Magnusson and Kligman scale (provided control group yields Grade < 1)	Non-sensitizer
Irritation: Intracutaneous Reactivity ISO 10993-23:2021	The test requirements are met if the difference between the test mean score and the control mean score is 1.0 or less and the test does not fail at any observation period. Differences of less than 0 are reported as 0.	Non-irritant

Conclusion:

The performance characteristics and the test results demonstrate that the 072 Aspiration System meets the test acceptance criteria, performs as well as, and is substantially equivalent to the predicate device, Penumbra System® [JET™ 7 Reperfusion Catheter with MAX Delivery Device (JET™ 7MAX)] (K191946), and reference devices.