August 29, 2024

Alembic, LLC
Lisa Yen
Director of Regulatory and Quality
627 National Avenue
Mountain View, California 94043

Re: K232971
Trade/Device Name: APRO 55 Catheter and Alembic Aspiration Tubing
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NRY

Dear Lisa Yen:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated February 29, 2024. Specifically, FDA is updating this SE Letter as an administrative correction to update the 510(k) Summary to reflect the biocompatibility testing conducted in support of the APRO 55 Catheter.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Naira Muradyan, Ph.D., OHT5: Office of Neurological and Physical Medicine Devices, 240-402-4918, Naira.Muradyan@fda.hhs.gov.

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

February 29, 2024

Alembic, LLC
Lisa Yen
Director of Regulatory and Quality
627 National Avenue
Mountain View, California 94043

Re: K232971
Trade/Device Name: APRO 55 Catheter and Alembic Aspiration Tubing
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NRY
Dated: January 26, 2024
Received: January 29, 2024

Dear Lisa Yen:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Naira Muradyan -S

Naira Muradyan, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
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)*
K232971

Device Name
APRO 55 Catheter and Alembic Aspiration Tubing

Indications for Use *(Describe)*
The APRO 55 Catheter with an aspiration pump and the Alembic Aspiration Tubing is intended 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.

The Alembic Aspiration Tubing is intended to connect the APRO 55 Catheter to the aspiration 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

510(k) Number: K232971

This 510(k) Summary is provided in accordance with the requirements of 21 CFR §807.92.

1) Submitter information

Submitter: Alembic, LLC
627 National Ave.
Mountain View, CA 94043

Contact: Lisa Yen
Director of Regulatory and Quality
Telephone Number: (650) 388-5087
Fax: (650) 390-0107
Email: lyen@alembicllc.com

Date Prepared: Mar 05, 2024

2) Device Name and Classification

Trade/Proprietary Name: APRO® 55 Catheter and Alembic Aspiration Tubing

Common Name: Catheter, Thrombus Retriever

Classification Name: Percutaneous Catheter, 21 CFR 870.1250

Regulatory Class: Class II

Product Code: NRY

Review Panel: Neurology

3) Legally Marketed Predicate Device and Reference Device

Predicate Device: K173841 AXS Catalyst Distal Access Catheter as part of the AXS Universal Aspiration System

Reference Device: K223545 APRO® 70 Catheter and Alembic Aspiration Tubing

4) Device Description

The APRO 55 Catheter is a single-lumen, braid and coil reinforced catheter. The APRO 55 Catheter is designed to remove thrombus from the vasculature using aspiration. The APRO 55 Catheter targets aspiration from a suction pump directly to the thrombus to remove thrombus from an occluded vessel. The APRO 55 Catheter is introduced through a guide catheter or long femoral sheath and into the intracranial vasculature and guided over a neurovascular guidewire under fluoroscopic visualization to the site of the primary occlusion. The distal shaft has a hydrophilic coating to aid navigation through the vasculature. A radiopaque marker is located at the distal end of the catheter for visualization under fluoroscopy. For the

aspiration source, the APRO 55 Catheter is used in conjunction with an aspiration pump with pre-specified performance parameters that is connected using the Alembic Aspiration Tubing, along with a legally marketed canister and accessories kit. The APRO 55 Catheter is available in lengths of 125 cm and 137 cm and is provided with an introducer sheath.

The Alembic Aspiration Tubing connects the APRO 55 Catheter to the aspiration pump. The flow control valve allows control of the aspiration flow using an ON/OFF switch. It is available in one size.

5) Indications for Use

The APRO 55 Catheter with an aspiration pump and the Alembic Aspiration Tubing is intended 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.

The Alembic Aspiration Tubing is intended to connect the APRO 55 Catheter to the aspiration pump.

6) Technological Characteristics Comparison

Alembic has demonstrated the APRO 55 Catheter and Alembic Aspiration Tubing are substantially equivalent to the predicate AXS Catalyst Distal Access Catheter based on the similarity in materials, similarity in design concept, and the same fundamental operating principles. A comparison of the APRO 55 Catheter with the predicate device is summarized in **Table 1** below. There are no changes to the Alembic Aspiration Tubing compared to that included as part of the K223545 submission.

Table 1 – APRO 55 Catheter Comparison with the Predicate Device and Reference Device

Category	**Subject Device** **APRO 55 Catheter and Alembic Aspiration Tubing**	**Predicate Device** **AXS Catalyst Distal Access Catheter as part of the AXS Universal Aspiration System**	**Reference Device** **APRO 70 Catheter and Alembic Aspiration Tubing**
510(k) Number	K232971	K173841	K223545
Regulatory Class	Identical to predicate	Class II, 21 CFR 870.1250, NRY	Class II, 21 CFR 870.1250, NRY
Indications for Use	The APRO 55 Catheter with an aspiration pump and the Alembic Aspiration Tubing is intended 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	The AXS Catalyst Distal Access Catheter as part of the AXS Universal Aspiration System is indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (in the internal carotid, middle cerebral - M1 and M2	The APRO 70 Catheter with an aspiration pump and the Alembic Aspiration Tubing is intended 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

Category	**Subject Device** **APRO 55 Catheter and Alembic Aspiration Tubing**	**Predicate Device** **AXS Catalyst Distal Access Catheter as part of the AXS Universal Aspiration System**	**Reference Device** **APRO 70 Catheter and Alembic Aspiration Tubing**
	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. The Alembic Aspiration Tubing is intended to connect the APRO 55 Catheter to the aspiration pump.	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.	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. The Alembic Aspiration Tubing is intended to connect the APRO 70 Catheter to the aspiration pump.
Principles of Operation	Same as predicate, reference	Using conventional catheterization techniques under fluoroscopic guidance, the catheter is advanced into the target vessel over an appropriate neurovascular guidewire. The catheter is positioned proximal to the thrombus to aspirate.	Using conventional catheterization techniques under fluoroscopic guidance, the catheter is advanced into the target vessel over an appropriate neurovascular guidewire. The catheter is positioned proximal to the thrombus to aspirate.
Materials			
Hub	Same as predicate	Nylon	Polycarbonate
Adhesive	Same as reference	None	Cyanoacrylate
Strain Relief	Same as reference	Thermoplastic rubber	Santoprene (thermoplastic elastomer)
Liner	Same as reference	Polytetrafluoroethylene (PTFE)	PTFE/Tecoflex composite
Shaft Coil or Braid	Same as reference	Stainless steel with nitinol wire and polymer fiber	304V stainless steel braid 304V stainless steel coil
Extrusions	Same as reference	Pebax, Nylon	Thermoplastic polyurethanes, thermoplastic elastomer
Marker Band	Same as predicate, reference	Platinum/ iridium	Platinum/ iridium
Adhesive	Same as reference	Cyanoacrylate	None
Coating	Same as predicate, reference	Hydrophilic coating	Hydrophilic coating
Dimensions			
Proximal Outer Diameter	0.066 inch	5.6 F (0.073 inch) 6.0 F (0.078 inch)	0.083 inch
Distal Outer Diameter	0.066 inch	5.3 F (0.069 inch) 5.4 F (0.070 inch)	0.083 inch
Inner Diameter (ID)	0.055 inch	0.058 inch, 0.060 inch	0.070 inch
Effective Length	125, 137 cm	115, 132 cm	125, 132, 135 cm
Coated Length	90, 102 cm	65, 82 cm	90, 97, 100 cm
Tip Shape	Same as predicate, reference	Straight	Straight
Accessories			
Introducer Sheath	Same as predicate, reference	Yes	Yes
Rotating Hemostasis Valve	Same as reference	Yes	None

Category	Subject Device APRO 55 Catheter and Alembic Aspiration Tubing	Predicate Device AXS Catalyst Distal Access Catheter as part of the AXS Universal Aspiration System	Reference Device APRO 70 Catheter and Alembic Aspiration Tubing
Packaging Materials			
Pouch	Same as predicate, reference	Nylon/polyethylene/Tyvek	Nylon/polyethylene/Tyvek
Packaging Tube	Same as predicate, reference	Polyethylene	Polyethylene
Packaging Card	Same as predicate, reference	Yes	Polyethylene
Shelf Carton	Same as predicate, reference	Solid bleached sulfate paperboard	Solid bleached sulfate paperboard
Other			
Sterilization	Same as predicate, reference	Ethylene oxide	Ethylene oxide
Shelf Life	Same as reference	2 years	6 months
Use	Same as predicate, reference	Sterile, single use, disposable	Sterile, single use, disposable
Alembic Aspiration Tubing			
Aspiration Tubing	Same as reference	300 cm length Tubing ID = 0.218 inch	110 inch length Tubing ID = 0.110 inch

7) Performance Data

Alembic performed non-clinical bench testing in accordance with the same design controls, protocols, and test methods as for the reference device APRO 70 Catheter (K223545). The results demonstrate substantial equivalence of the subject APRO 55 Catheter and Alembic Aspiration Tubing to the legally marketed predicate device.

A. Design Verification Testing – Non-Clinical Bench

Included in **Table 2** is the description of bench performance tests that were conducted to support substantial equivalence determination.

Table 2 – Summary of Non-Clinical Bench Test Results

Test	Acceptance Criteria	Conclusion
Visual and Dimensional Characteristics	Catheter meets the visual and dimensional specifications.	The APRO 55 Catheter met the acceptance criteria.
	Introducer Sheath meets the visual and dimensional specifications.	The Introducer Sheath met the acceptance criteria.
Particulate	Catheter meets the acceptance criteria. Subject device was evaluated with a predicate device under the same test conditions.	The APRO 55 Catheter met the acceptance criteria.
Vacuum Integrity	Catheter is free from collapse and loss of vacuum between aspiration source and catheter tip.	The APRO 55 Catheter met the acceptance criteria.
Kink Resistance	Catheter shaft shall not kink at clinically relevant radii.	The APRO 55 Catheter met the acceptance criteria.
Catheter Hub Leakage	Catheter does not leak into hub assembly during aspiration, with methods specified in ISO 10555-1, Annex D.	The APRO 55 Catheter met the acceptance criteria.
Hub Compatibility	Hub meets the requirements per EN ISO 80369-7	The APRO 55 Catheter met the acceptance criteria.

Test	Acceptance Criteria	Conclusion
Catheter Torque Strength	Catheter must withstand the minimum required number of rotations without breakage and without kinking compared to legally marketed devices.	The APRO 55 Catheter met the acceptance criteria.
Dynamic Burst Pressure	No damage to catheter with dynamic pressure.	The APRO 55 Catheter met the acceptance criteria.
Fluid Leakage	Catheter must withstand pressure with methods per ISO 10555-1 Annex C.	The APRO 55 Catheter met the acceptance criteria.
Static Burst	Catheter must withstand pressures anticipated for clinical use.	The APRO 55 Catheter met the acceptance criteria.
Tensile Strength of Catheter Hub and Shaft	Catheter hub and shaft must meet tensile strength specification.	The APRO 55 Catheter met the acceptance criteria.
Tensile Strength of Catheter Tip	Catheter tip must meet tip tensile strength specification.	The APRO 55 Catheter met the acceptance criteria.
Delivery and Retrieval Force	Catheter delivery and retrieval force must be acceptable. Forces were compared to a predicate.	The APRO 55 Catheter met the acceptance criteria.
Tip Buckling Force	Catheter tip buckling force must be acceptable. Forces were compared to a predicate.	The APRO 55 Catheter met the acceptance criteria.
Simulated Use including Clot Retrieval	When used per the Instructions for Use with accessory devices in an anatomical neurovascular model, the Catheter and Aspiration Tubing must meet functionality specifications. Clot retrieval from various locations of the anatomical model was performed using the subject device system.	The APRO 55 Catheter and Alembic Aspiration Tubing met the acceptance criteria.

B. Design Verification Testing – Animal

Substantial equivalence was established based on non-clinical performance data. Animal data were not deemed necessary.

C. Sterilization and Shelf-Life

The APRO 55 Catheter and Alembic Aspiration Tubing are sterilized using an ethylene oxide sterilization cycle that was verified to a sterility assurance level of 1×10^{-6} in accordance with ISO 11135. Aging studies for the APRO 55 Catheter and Alembic Aspiration Tubing have established that the subject device and packaging remain functional for the labeled expiration date. Aging studies for packaging integrity, seal strength, and device functionality were performed and met the acceptance criteria.

D. Biocompatibility

Biocompatibility testing has been completed for the APRO 55 Catheter in accordance with ISO 10993-1 and the device is deemed non-toxic (local or systemic), non-sensitizing, not locally irritating or otherwise harmful. Test results obtained were acceptable for the intended use as shown in **Table 3**. The thrombogenicity evaluation of the APRO 55 Catheter was supplemented by the prior *in vivo* thrombogenicity evaluation of the reference device, APRO 70 Catheter, in a good laboratory practice animal study.

Biocompatibility studies for the Alembic Aspiration Tubing, that is unchanged from K223545, have previously established that it is biocompatible.

Table 3 – Biocompatibility Test Results

Test	Results	Conclusions
Sensitization (Guinea Pig Maximization)	The APRO 55 Catheter did not elicit a sensitization response.	Non-sensitizing
Irritation/Intracutaneous Reactivity	The APRO 55 Catheter demonstrated no evidence of irritation.	Non-Irritant
Cytotoxicity (MEM Elution, L929 cells)	The APRO 55 Catheter did not elicit a cytotoxic response at 24 hours and 48 hours.	Non-cytotoxic
Hemolysis – Indirect	There were no significant differences between the test article extract and negative control article results.	Non-hemolytic
Hemolysis – Direct	There were no differences between the hemolytic index of the test article and the negative control.	Non-hemolytic
Partial Thromboplastin Time (PTT)	The average clotting time of the test article was greater than vehicle control and negative control.	Acceptable clotting times
SC5b9 Complement Activation	The Sc5b9 concentration of the test article was statistically less than the positive control and was not statistically higher than the negative control.	Acceptable
Acute Systemic Toxicity	No weight loss, mortality, or evidence of systemic toxicity from the extract exposure to the mice.	Non-toxic
Material-Mediated Pyrogenicity	All individual rabbits for both the test article and negative control showed a total rise in temperature of < 0.5 ºC and were determined to be nonpyrogenic.	Non-pyrogenic

E. Clinical Testing

Substantial equivalence was established based on non-clinical performance data. Human clinical data were not deemed necessary.

8) Conclusion

Based on the comparison of the technological characteristics and the non-clinical testing, the subject device is found to be substantially equivalent to the predicate device. The differences in technological characteristics do not raise new questions of safety and effectiveness. Testing was conducted to demonstrate that the subject device meets the specifications and performs as intended.