February 17, 2023

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

Re: K223545
Trade/Device Name: APRO 70 Catheter and Alembic Aspiration Tubing
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NRY
Dated: November 23, 2022
Received: November 25, 2022

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 (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,
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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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223545

Device Name
APRO 70 Catheter and Alembic Aspiration Tubing

Indications for Use *(Describe)*
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 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.

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

510(k) Number: K223545

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
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Email: lyen@alembicllc.com

Date Prepared: February 16, 2023

2) Device Name and Classification

Trade/Proprietary Name: APRO™ 70 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 and Reference Devices

Primary Predicate Device: K142458 Penumbra System ACE 68 Reperfusion Catheter

Reference Device: K173200 SOFIA Plus Aspiration Catheter

4) Device Description

The APRO 70 Catheter is a single-lumen, braid and coil reinforced catheter. The APRO 70 Catheter is designed to remove thrombus from the vasculature using aspiration. The APRO

70 Catheter targets aspiration from the suction pump directly to the thrombus to remove thrombus from an occluded vessel. The APRO 70 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 70 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 70 Catheter is available in lengths of 125 cm, 132 cm, and 135 cm and is provided with an introducer sheath.

The Alembic Aspiration Tubing connects the APRO 70 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 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 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.

6) Technological Characteristics Comparison

Alembic has demonstrated the APRO 70 Catheter and Alembic Aspiration Tubing are substantially equivalent to the predicate device based on the similarity in materials, similarity in design concept, and the same fundamental operating principles. A comparison of the APRO 70 Catheter and Alembic Aspiration Tubing with the predicate device is summarized in **Table 1** below.

Table 1 – APRO 70 Catheter and Alembic Aspiration Tubing Comparison with the Predicate and Reference Devices

Device Characteristic	**Subject Device** APRO 70 Catheter and Alembic Aspiration Tubing	**Predicate Device** Penumbra System ACE 68 Reperfusion Catheter (K142458)	**Reference Device** SOFIA Plus Aspiration Catheter (K173200)
Regulatory Class	II, 21 CFR 870.1250	Same as subject device	Same as subject device
Product Code	NRY	Same as subject device	Same as subject device

Device Characteristic	**Subject Device** APRO 70 Catheter and Alembic Aspiration Tubing	**Predicate Device** Penumbra System ACE 68 Reperfusion Catheter (K142458)	**Reference Device** SOFIA Plus Aspiration Catheter (K173200)
Indication for Use	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 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.	The Penumbra System 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. The Reperfusion Catheters ACE 64 and ACE 68 are intended for use in revascularization within the Internal Carotid Artery (ICA) within 8 hours of symptom onset.	The SOFIA Plus Aspiration Catheter with the Gomco 405 Aspiration Pump and MicroVention Tubing Kit 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.
Principles of Operation	Using conventional catheterization techniques under fluoroscopic guidance, advance the catheter into the target vessel over an appropriate neurovascular guidewire. Position the catheter proximal to the thrombus to aspirate.	Same as subject device	Same as subject device
Accessory Devices Provided	Introducer sheath	Peelable sheath, rotating hemostasis valve, shaping mandrel	Introducer sheath, shaping mandrel
Materials			
Hub	Polycarbonate	Nylon (Grilamid)	Nylon (Grilamid)
Strain Relief	Santoprene (thermoplastic elastomer)	Nylon (Grilamid) / 304 stainless steel	Polyurethane
Liner	Polytetrafluoroethylene (PTFE)/Tecoflex composite	Not described	Polytetrafluoroethylene/ polyolefin elastomer
Shaft Coil and Braid	304V stainless steel braid 304V stainless steel coil	304V stainless steel braid nitinol coil	Stainless steel braid Stainless steel coil

Device Characteristic	Subject Device APRO 70 Catheter and Alembic Aspiration Tubing	Predicate Device Penumbra System ACE 68 Reperfusion Catheter (K142458)	Reference Device SOFIA Plus Aspiration Catheter (K173200)
Extrusions	Thermoplastic polyurethanes, thermoplastic elastomer	Thermoplastic polyurethane (Pellethane and Tecoflex), polyether block amide (Pebax), polyamide (Vestamid)	Polyurethane elastomer (polyblend and Pellethane), polyether block amide (Pebax), polyamide (Grilamid)
Marker band	Platinum/ iridium	Same as subject device	Same as subject device
Coating	Hydrophilic coating	Same as subject device	Same as subject device
Dimensions			
Proximal Outer Diameter (OD)	0.083 inch	0.084 inch max	Same as subject device
Proximal Inner Diameter (ID)	0.070 inch	0.068 inch min	Same as subject device
Distal OD	0.083 inch	0.084 inch max	0.082 inch
Distal ID	0.070 inch	0.068 inch min	Same as subject device
Effective Lengths	125, 132, 135 cm	115, 120, 125, 127, 132 cm	125 - 131 cm
Coated Length	90, 97, 100 cm	30 cm	Unknown
Tip Shape	Straight	Same as subject device	Same as subject device
Accessories			
Peelable Sheath	Pebax	PTFE	Same as subject device
Packaging Materials			
Pouch	Nylon/polyethylene/Tyvek	Polyester/polyethylene/ Tyvek	Polyester/polyethylene/ Tyvek
Packaging Tube	High density polyethylene	Polyethylene	Polyethylene
Packaging Card	High density polyethylene	Polyethylene	Polyethylene
Display Carton	Solid bleached sulfate paperboard	Same as subject device	Same as subject device
Other			
Sterilization	Ethylene oxide	Same as subject device	Same as subject device
Shelf-Life	6 months	36 months	36 months
Use	Single use, disposable	Same as subject device	Same as subject device
Alembic Aspiration Tubing			
Aspiration Tubing	110 inch length Tubing ID = 0.110 inch	112 inch length Tubing ID = 0.110 inch	112 inch length Tubing ID = 0.110 inch

7) Performance Data

A. Testing Summary

Alembic performed non-clinical bench, animal, sterility, shelf-life, and biocompatibility testing. The results demonstrate substantial equivalence of the APRO 70 Catheter and Alembic Aspiration Tubing to the legally marketed predicate device.

B. Design Verification Testing – Non-Clinical Bench

Performance testing was conducted to support the APRO 70 Catheter and Alembic Aspiration

Tubing submission. The results of the design verification and validation testing performed confirm that the APRO 70 Catheter and Alembic Aspiration Tubing conform to the pre-defined specifications and meet test acceptance criteria. Testing is shown in **Table 2**.

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 70 Catheter met the acceptance criteria.
	Introducer Sheath meets the visual and dimensional specifications.	The Introducer Sheath met the acceptance criteria.
	Aspiration Tubing meets the visual and dimensional specifications.	The Alembic Aspiration Tubing 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 70 Catheter met the acceptance criteria.
Vacuum Integrity	Catheter with Aspiration Tubing is free from collapse and loss of vacuum between aspiration source and catheter tip.	The APRO 70 Catheter and Alembic Aspiration Tubing met the acceptance criteria.
Kink Resistance	Catheter distal shaft shall not kink.	The APRO 70 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 70 Catheter met the acceptance criteria.
Catheter Torque Strength	Catheter must withstand the minimum required number of rotations without breakage.	The APRO 70 Catheter met the acceptance criteria.
Dynamic Burst Pressure	No damage to catheter with dynamic pressure.	The APRO 70 Catheter met the acceptance criteria.
Fluid Leakage	Catheter must withstand pressure with methods specified in ISO 10555-1, Annex C.	The APRO 70 Catheter met the acceptance criteria.
Static Burst (Rupture)	Catheter must withstand pressures anticipated for clinical use.	The APRO 70 Catheter met the acceptance criteria.
Tensile Strength of Catheter Hub and Shaft	Catheter hub and shaft must meet tensile strength specification.	The APRO 70 Catheter met the acceptance criteria.
Tensile Strength of Catheter Tip	Catheter tip must meet tip tensile strength specification.	The APRO 70 Catheter met the acceptance criteria.
Tensile Strength of Aspiration Tubing	Aspiration Tubing junction must meet tensile strength specification.	The Alembic Aspiration Tubing met the acceptance criteria.
Simulated Use	When used per the Instructions for Use with accessory devices in an anatomical neurovascular model, the Catheter and Aspiration Tubing must meet functionality specifications.	The APRO 70 Catheter and Alembic Aspiration Tubing met the acceptance criteria.
Usability	The Catheter and Aspiration	The APRO 70 Catheter and

Test	Acceptance Criteria	Conclusion
	Tubing were used per the Instructions for Use with accessory devices in an anatomical neurovascular model and compared to a predicate.	Alembic Aspiration Tubing met the acceptance criteria.
Corrosion Resistance	Catheter must be corrosion resistant per ISO 10555-1, Annex A.	The APRO 70 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 70 Catheter met the acceptance criteria.
Tip Buckling Force	Catheter tip buckling force must be acceptable. Forces were compared to a predicate.	The APRO 70 Catheter met the acceptance criteria.

C. Design Verification Testing – Animal

Non-clinical animal testing comparing the safety, usability, and performance of the APRO 70 Catheter and Alembic Aspiration Tubing to the Penumbra System ACE 68 Reperfusion Catheter was conducted on a porcine model under Good Laboratory Practices (GLP). Sub-chronic (3-day) and chronic (30-day) time points were assessed. Device visibility under fluoroscopy and compatibility with ancillary devices were comparable between test and control devices and acceptable. No thrombus was noted on any of the APRO 70 Catheters or on the predicate Penumbra System ACE 68 Reperfusion Catheters during thrombogenicity assessment. Experimental clot aspiration was comparable and effective with both the APRO 70 Catheter and the predicate Penumbra System ACE 68 Reperfusion Catheter. Both catheters were shown to be safe to use in porcine vessels via angiography and vessel histology.

D. Sterilization and Shelf-Life

The APRO 70 Catheter and the 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 70 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.

E. Biocompatibility

Biocompatibility testing has been completed for the APRO 70 Catheter and Alembic Aspiration Tubing 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**.

Table 3 – Biocompatibility Test Results

Test	Results	Conclusions
Sensitization (Guinea Pig	The APRO Catheter did not elicit a sensitization Response.	Non-sensitizing

Test	Results	Conclusions
Maximization)	The Alembic Aspiration Tubing did not elicit a sensitization response.	Non-sensitizing
Irritation/Intracutaneous Reactivity	The APRO Catheter demonstrated no evidence of irritation.	Non-Irritant
	The Alembic Aspiration Tubing demonstrated no evidence of irritation.	Non-Irritant
Cytotoxicity (MEM Elution, L929 cells)	The APRO 70 Catheter did not elicit a cytotoxic response at 24 hours and 48 hours.	Non-cytotoxic
	The Alembic Aspiration Tubing did not elicit a cytotoxic response.	Non-cytotoxic
Hemolysis - Indirect	There were no significant differences between the test article and the negative control..	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	Acceptable - during use, the circulating blood dilutes by over 800X the exposure during the test, providing assurance that the use of the APRO 70 Catheter will not constitute a complement activation safety concern.	Acceptable
Thrombogenicity	No significant thrombus was observed on any of the subject catheters, and the device was determined to not show thrombogenic potential.	Non-thrombogenic
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

F. 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.