April 10, 2023

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

Re: K230695
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: March 10, 2023
Received: March 13, 2023

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,
Neurointerventional
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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)*
K230695

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: K230695

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: April 7, 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 Device

Predicate Device: K223545 APRO 70 Catheter and Alembic Aspiration Tubing

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 subject APRO 70 Catheter and Alembic Aspiration Tubing are substantially equivalent to the predicate based on the same materials, same design concept, and the same fundamental operating principles. A comparison of the APRO 70 Catheter with the predicate device is summarized in **Table 1** below. There are no changes to the Alembic Aspiration Tubing compared to K223545.

Table 1 – Subject APRO 70 Catheter Comparison with the Predicate Device

Category	**Subject Device** **APRO 70 Catheter**	**Predicate Device** **APRO 70 Catheter**
510(k) Number	K230695	K223545
Regulatory Class	Identical to predicate	Class II, 21 CFR 870.1250, NRY
Indications for Use	Identical to predicate	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.
Principles of Operation	Identical to predicate	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.

Category	Subject Device APRO 70 Catheter	Predicate Device APRO 70 Catheter
Accessory Devices Provided	Identical to predicate	Introducer sheath
Materials		
Hub	Identical to predicate	Polycarbonate
Strain Relief	Identical to predicate	Santoprene (thermoplastic elastomer)
Liner	Identical to predicate	Polytetrafluoroethylene/Tecoflex composite
Shaft Coil and Braid	Identical to predicate	304V stainless steel braid 304V stainless steel coil
Extrusions	Identical to predicate	Thermoplastic polyurethanes, thermoplastic elastomer
Marker Band	Identical to predicate	Platinum/ iridium
Coating	Identical to predicate	Hydrophilic Coating
Dimensions		
Proximal Outer Diameter (OD)	Identical to predicate	0.083 inch
Proximal Inner Diameter (ID)	Identical to predicate	0.070 inch
Distal OD	Identical to predicate	0.083 inch
Distal ID	Identical to predicate	0.070 inch
Effective Lengths	Identical to predicate	125, 132, 135 cm
Coated Length	Identical to predicate	90, 97, 100 cm
Tip Shape	Identical to predicate	Straight
Accessories		
Introducer Sheath	Identical to predicate	Pebax
Packaging Materials		
Pouch	Identical to predicate	Nylon/polyethylene/Tyvek
Packaging Tube	Identical to predicate	High density polyethylene
Packaging Card	Identical to predicate	High density polyethylene
Shelf Carton	Identical to predicate	Solid bleached sulfate paperboard
Other		
Sterilization	Identical to predicate	Ethylene oxide
Use Conditions	Identical to predicate	Sterile, single use, disposable
Shelf life	1 year	6 months

7) Performance Data

Alembic performed non-clinical bench testing in accordance with design controls, protocol, and test methods that were previously reviewed in a relevant prior pre-market submission. Included in **Table 2** is the description of each performance test that was conducted to support substantial equivalence determination. The results demonstrate substantial equivalence of the subject APRO 70 Catheter and Alembic Aspiration Tubing to the legally marketed predicate device.

A. Design Verification Testing – Non-Clinical Bench

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	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.
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.
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.

B. Design Verification Testing – Animal

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

C. Sterilization and Shelf-Life

Sterilization studies for the subject APRO 70 Catheter have established that the subject device remains sterile for the labeled expiration date. Additional sterilization data were not deemed necessary.

Aging studies for the subject APRO 70 Catheter have established that the subject device and packaging remains functional for the labeled expiration date. Aging studies for the subject device functionality were performed and met the acceptance criteria.

D. Biocompatibility

Biocompatibility studies for the predicate APRO 70 Catheter and Alembic Aspiration Tubing (K223545) have previously established that the subject device is biocompatible. Additional biocompatibility data were not deemed necessary because there are no changes to the design, material, or manufacturing of the APRO 70 Catheter and Alembic Aspiration Tubing compared to the predicate (K223545).

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 revised Instructions for Use and the extended shelf-life 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.