March 15, 2024

Alembic, LLC
℅ Prithul Bom
Most Responsible Person
Regulatory Technology Services
1000 Westgate Drive, Suite #510k
Saint Paul, Minnesota 55114

Re: K234115
Trade/Device Name: APRO 55 Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY, QJP
Dated: March 6, 2024
Received: March 6, 2024

Dear Prithul Bom:

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)*
K234115

Device Name
APRO 55 Catheter

Indications for Use *(Describe)*
The APRO 55 Catheter is indicated for use in facilitating the insertion and guidance of appropriately sized interventional devices into a selected blood vessel in the peripheral and neurovascular systems. The APRO 55 Catheter is also indicated for use as a conduit for retrieval devices.

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.***

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# 510(k) Summary

**510(k) Number: K234115**

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
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**Date Prepared:** March 13, 2024

## 2) Device Name and Classification

**Trade/Proprietary Name:** APRO® 55 Catheter

**Common Name:** Percutaneous Catheter

**Classification Name:** Percutaneous Catheter, 21 CFR 870.1250
Catheter, Percutaneous, Neurovasculature, 21 CFR 870.1250

**Regulatory Class:** Class II

**Product Codes:** DQY, QJP

**Review Panel:** Cardiovascular, Neurology

## 3) Legally Marketed Predicate Device and Reference Device

**Predicate Device:** K151667 AXS Catalyst Distal Access Catheter
**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 facilitate the insertion and guidance of interventional devices into peripheral and neuro vasculature. Using standard catheterization techniques under fluoroscopic guidance, the APRO 55 Catheter is introduced through a guide catheter or guide sheath and over a guidewire into the target vasculature. The distal segment of the catheter shaft has a hydrophilic coating to aid navigation through the vasculature. A radiopaque marker is located at the distal tip of the catheter for visualization under fluoroscopy. The APRO 55 Catheter is provided with an Introducer Sheath.

## 5) Indications for Use

The APRO 55 Catheter is indicated for use in facilitating the insertion and guidance of appropriately sized interventional devices into a selected blood vessel in the peripheral and neurovascular systems. The APRO 55 Catheter is also indicated for use as a conduit for retrieval devices.

## 6) Technological Characteristics Comparison

Alembic has demonstrated that the APRO 55 Catheter is 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 55 Catheter with the predicate device and reference device is summarized in **Table 1** below.

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

| **Category** | **Subject Device**<br>**APRO 55 Catheter** | **Predicate Device**<br>**AXS Catalyst Distal Access Catheter** | **Reference Device**<br>**APRO 70 Catheter and Alembic Aspiration Tubing** |
|---|---|---|---|
| 510(k) Number | K234115 | K151667 | K223545 |
| Regulatory Class | Class II, 21 CFR 870.1250, DQY, QJP | Class II, 21 CFR 870.1250, DQY | Class II, 21 CFR 870.1250, NRY |
| Indications for Use | The APRO 55 Catheter is indicated for use in facilitating the insertion and guidance of appropriately sized interventional devices into a selected blood vessel in the peripheral and neurovascular systems. The APRO 55 Catheter is also indicated for use as a conduit for retrieval devices. | The AXS Catalyst Distal Access Catheter is indicated for use in facilitating the insertion and guidance of appropriately sized interventional devices into a selected blood vessel in the peripheral and neurovascular systems. The AXS Catalyst Distal Access Catheter is also indicated for use as a conduit for retrieval devices. | 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.<br>The Alembic Aspiration Tubing is intended to connect the APRO 70 Catheter to the aspiration pump. |
| **Materials** | | | |
| Hub | Nylon | Nylon | Polycarbonate |
| Adhesive | Cyanoacrylate | None | Cyanoacrylate |
| Strain Relief | Thermoplastic elastomer | Thermoplastic rubber | Thermoplastic elastomer |
| Liner | Polytetrafluoroethylene (PTFE)/Tecoflex composite | PTFE | PTFE/Tecoflex composite |
| Shaft Coil or Braid | 304V stainless steel braid 304V stainless steel coil | Stainless steel with nitinol wire and polymer fiber | 304V stainless steel braid 304V stainless steel coil |
| Extrusions | Thermoplastic polyurethanes, thermoplastic elastomer | Pebax, Nylon | Thermoplastic polyurethanes, thermoplastic elastomer |
| Marker Band | Platinum/ iridium | Platinum/ iridium | Platinum/ iridium |
| Adhesive | None | Cyanoacrylate | None |
| Coating | Hydrophilic coating, identical | Hydrophilic coating | Hydrophilic coating |

| Category | Subject Device<br>APRO 55 Catheter | Predicate Device<br>AXS Catalyst Distal Access Catheter | Reference Device<br>APRO 70 Catheter and Alembic Aspiration Tubing |
|---|---|---|---|
| | to reference device | | |
| **Dimensions** | | | |
| Proximal Outer Diameter | 0.066 inch | 5.6 F (0.073 inch)<br>6.0 F (0.078 inch) | 0.083 inch |
| Distal Outer Diameter | 0.066 inch | 5.3 F (0.069 inch)<br>5.4 F (0.070 inch) | 0.083 inch |
| Inner Diameter | 0.055 inch | 0.058 inch, 0.060 inch | 0.070 inch |
| Effective Lengths | 125, 137 cm | 115, 132 cm | 125, 132, 135 cm |
| Coated Length | 90, 102 cm | 65, 82 cm | 90, 97, 100 cm |
| Tip Shape | Straight | Straight | Straight |
| **Accessories** | | | |
| Introducer Sheath | Yes | Yes | Yes |
| Rotating Hemostasis Valve | None | Yes | None |
| **Packaging Materials** | | | |
| Pouch | Nylon/polyethylene/ Tyvek | Nylon/polyethylene/ Tyvek | Nylon/polyethylene/ Tyvek |
| Packaging Tube | Polyethylene | Polyethylene | Polyethylene |
| Packaging Card | Yes | Yes | Yes |
| Shelf Carton | Solid bleached sulfate paperboard | Solid bleached sulfate paperboard | Solid bleached sulfate paperboard |
| **Other** | | | |
| Sterilization | Ethylene oxide | Ethylene oxide | Ethylene oxide |
| Shelf Life | 6 months | 2 years | 6 months |
| Use Conditions | Sterile, single use, disposable | Sterile, single use, disposable | Sterile, single use, disposable |

## 7) Performance Data

Alembic performed non-clinical bench, sterility, shelf-life, and biocompatibility testing. The results demonstrate substantial equivalence of the APRO 55 Catheter to the legally marketed predicate device.

### A. Design Verification Testing – Non-Clinical Bench

Performance testing was conducted to support the APRO 55 Catheter submission. The results of the design verification and validation testing performed confirm that the APRO 55 Catheter conforms to the predefined specifications and met test acceptance criteria. A summary of the 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 55 Catheter 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. |
| Kink Resistance | Catheter shaft shall not kink at clinically relevant radii. | The APRO 55 Catheter met the acceptance criteria. |
| Hub Air Leakage | Catheter does not leak air into hub | The APRO 55 Catheter met the |

| Test | Acceptance Criteria | Conclusion |
|---|---|---|
| | assembly with methods specified in ISO 10555-1, Annex D. | acceptance criteria. |
| Hub Compatibility | Catheter meets the requirements specified in ISO 80369-7. | The APRO 55 Catheter met the acceptance criteria. |
| 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. |
| Liquid Leakage | Catheter must withstand pressure with methods specified in 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. |
| Hub and Shaft Tensile Strength | Catheter hub and shaft must meet tensile strength specification. | The APRO 55 Catheter met the acceptance criteria. |
| Tip Tensile Strength | Catheter tip must meet tip tensile strength specification. | 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. |
| 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. |
| Simulated Use | When used per the Instructions for Use with accessory devices in an anatomical neurovascular model, the Catheter must meet functionality specifications. | The APRO 55 Catheter 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**

The APRO 55 Catheter is sterilized using an ethylene oxide sterilization cycle that was verified to a sterility assurance level of $1 \times 10^{-6}$ in accordance with ISO 11135.

Aging studies for the APRO 55 Catheter have established that the subject device and packaging remain functional for the labeled expiration date. Aging studies for packaging integrity, seal strength, and the 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.

**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.