May 1, 2025

Alembic, LLC
Stina Almaleh
Regulatory and Quality Engineer
627 National Avenue
Mountain View, California 94043

Re: K251014
Trade/Device Name: APRO 45 Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY, QJP
Dated: April 1, 2025
Received: April 2, 2025

Dear Stina Almaleh:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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
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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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251014

Device Name
APRO 45 Catheter

Indications for Use *(Describe)*
The APRO 45 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 45 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.

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510(k) Summary

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: Stina Almaleh
Regulatory and Quality Engineer
Email: salmaleh@alembicllc.com
Telephone Number: (650) 388-5080

Date Prepared: April 29, 2025

2) Device Name and Classification

Trade/Proprietary Name: APRO® 45 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

Predicate Device: K234115 APRO 55 Catheter

4) Device Description

The APRO 45 Catheter is a single-lumen, braid and coil reinforced catheter. The APRO 45 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 45 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 45 Catheter is provided with an Introducer Sheath. The APRO 45 Catheter contains animal derived materials made from tallow derivatives.

5) Indications for Use

The APRO 45 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 45 Catheter is also indicated for use as a conduit for retrieval devices.

6) Technological Characteristics Comparison

Alembic has demonstrated that the APRO 45 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 45 Catheter with the predicate is summarized in **Table 1** below.

Table 1. APRO 45 Catheter Comparison with the Predicate Device

Category	Subject Device APRO 45 Catheter	Predicate Device APRO 55 Catheter
510(k) Number	K251014	K234115
Regulatory Class	Same as predicate.	Class II, 21 CFR 870.1250, DQY, QJP
Indications for Use	The APRO 45 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 45 Catheter is also indicated for use as a conduit for retrieval devices.	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.
Materials		
Hub	Same as predicate.	Nylon
Adhesive	Same as predicate.	Cyanoacrylate
Strain Relief	Same as predicate.	Thermoplastic elastomer
Liner	Polytetrafluoroethylene (PTFE)/Pebax composite	PTFE/Tecoflex composite
Shaft Coil or Braid	Same as predicate.	304V stainless steel braid 304V stainless steel coil
Extrusions	Polyether block amide	Thermoplastic polyurethanes, thermoplastic elastomer
Marker Band	Same as predicate.	Platinum/ iridium
Coating	Same as predicate.	Hydrophilic coating
Dimensions		
Proximal Outer Diameter	0.060 inch	0.066 inch
Distal Outer Diameter	0.058 inch	0.066 inch
Inner Diameter	0.045 inch	0.055 inch
Effective Lengths	115, 125, 146, 160 cm	125, 137 cm
Coated Length	60 cm	90, 102 cm
Tip Shape	Same as predicate.	Straight
Accessories		
Introducer Sheath	Same as predicate.	Yes
Packaging Materials		
Pouch	Same as predicate.	Nylon/polyethylene/ Tyvek
Packaging Tube	N/A	Polyethylene
Packaging Hoop Coil	Polyethylene	N/A
Packaging Card	Same as predicate.	Polyethylene
Shelf Carton	Same as predicate.	Solid bleached sulfate paperboard
Other		
Sterilization	Same as predicate.	Ethylene oxide
Shelf Life	1 year	6 months
Use Conditions	Same as predicate.	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 45 Catheter to the legally marketed predicate device.

A. Design Verification Testing – Non-Clinical Bench

Bench performance testing was conducted to support the APRO 45 Catheter submission. The results of the design verification and validation testing confirm that the APRO 45 Catheter conforms to the predefined specifications and meets the 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 45 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 45 Catheter met the acceptance criteria.
Kink Resistance	Catheter shaft shall not kink at clinically relevant radii.	The APRO 45 Catheter met the acceptance criteria.
Hub Air Leakage	Catheter does not leak air into hub assembly with methods specified in ISO 10555-1, Annex D.	The APRO 45 Catheter met the acceptance criteria.
Hub Compatibility	Catheter meets the requirements specified in ISO 80369-7.	The APRO 45 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 45 Catheter met the acceptance criteria.
Dynamic Burst Pressure	No damage to catheter with dynamic pressure.	The APRO 45 Catheter met the acceptance criteria.
Liquid Leakage	Catheter must withstand pressure with methods specified in ISO 10555-1, Annex C.	The APRO 45 Catheter met the acceptance criteria.
Static Burst	Catheter must withstand pressures anticipated for clinical use.	The APRO 45 Catheter met the acceptance criteria.
Hub and Shaft Tensile Strength	Catheter hub and shaft must meet tensile strength specification.	The APRO 45 Catheter met the acceptance criteria.
Tip Tensile Strength	Catheter tip must meet tip tensile strength specification.	The APRO 45 Catheter met the acceptance criteria.
3-Point Bend	Catheter 3-Point Bend force must be acceptable. Forces were compared to the predicate.	The APRO 45 Catheter met the acceptance criteria.
Delivery and Retrieval Force	Catheter delivery and retrieval force must be acceptable. Forces were compared to the predicate.	The APRO 45 Catheter met the acceptance criteria.
Simulated Use	When used per the Instructions for Use with accessory devices in an anatomical neurovascular model and during simulated clot retrieval, the Catheter must meet functionality specifications including compatibility with a stent retriever.	The APRO 45 Catheter met the acceptance criteria.
Corrosion Resistance	Catheter shall show no signs of corrosion when tested in accordance with ISO 10555-1, Annex A.	The APRO 45 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 45 Catheter is 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 45 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 45 Catheter as an externally communicating device with circulating blood contact for a limited (≤ 24 hours) duration in accordance with ISO 10993-1 and the FDA Guidance, *"Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"."*

Table 3. Summary of Biocompatibility Test Results

Test	Results	Conclusions
Sensitization (Guinea Pig Maximization)	The APRO 45 Catheter did not elicit a sensitization response.	Non-sensitizing
Irritation/Intracutaneous Reactivity	The APRO 45 Catheter demonstrated no evidence of irritation.	Non-irritant
Cytotoxicity (MEM Elution, L929 cells)	The APRO 45 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
Thrombogenicity – Partial Thromboplastin Time (PTT)	The average clotting time of the test article was not significantly different from the vehicle and negative control.	Non-thrombogenic
Thrombogenicity – Platelet Leukocyte Count	The test article performed similar to comparator and negative controls.	
Thrombogenicity – Comparative Surface and Geometry Assessment	Comparative surface assessment using 40x optical microscopy at representative locations of the subject device and the predicate device did not find any differences in the roughness or presence of any defects. The subject device has similar surface morphology as the predicate device APRO 55 Catheter.	
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

Table 3. Summary of Biocompatibility Test Results		
Test	**Results**	**Conclusions**
Material-Mediated Pyrogenicity	All individual rabbits for both the test article and negative control showed a total rise in temperature of < 0.5ºC 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.