April 29, 2025

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

Re: K250962
Trade/Device Name: APRO 55 Intermediate Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY, QJP
Dated: March 28, 2025
Received: March 31, 2025

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.

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
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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)*
K250962

Device Name
APRO 55 Intermediate Catheter

Indications for Use *(Describe)*
The APRO 55 Intermediate 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 Intermediate 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 K250962

Date Prepared: April 24, 2025

Applicant Name	Alembic, LLC
Applicant Address	627 National Avenue, Mountain View, CA 94043 United States
Applicant Contact Telephone	650-388-5087
Applicant Contact	Lisa Yen
Applicant Contact Email	lyen@alembicllc.com
Device Trade Name	APRO® 55 Intermediate Catheter
Common Name	Percutaneous catheter
Classification Name	Percutaneous Catheter (DQY) Catheter, Percutaneous, Neurovasculature (QJP)
Regulation Number	21 CFR 870.1250
Product Codes	DQY, QJP
Predicate Device	K234115 APRO® 55 Catheter
Reference Device	K243297 APRO® 70 Swift Catheter

Device Description

The APRO 55 Intermediate Catheter is a single-lumen, braid and coil reinforced catheter. The 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 Intermediate 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 catheter is provided with an Introducer Sheath.

Indications for Use

The APRO 55 Intermediate 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 Intermediate Catheter is also indicated for use as a conduit for retrieval devices.

Technological Characteristics Comparison

The subject device has the same intended use and is identical to the predicate device, APRO 55 Catheter (K234115), in terms of technology, principle of operation, materials, sterilization method, and performance. The only difference lies in the packaging configuration. A comparison of the subject, predicate, and reference devices is provided in Table 1 below.

Table 1. Comparison with the Predicate and Reference Devices			
Category	**Subject Device** **APRO 55 Intermediate Catheter**	**Predicate Device** **APRO 55 Catheter**	**Reference device** **APRO 70 Swift Catheter**
510(k) Number	K250962	K234115	K243297
Regulatory Class, Product Code	Same	Class II, 21 CFR 870.1250, DQY, QJP	Class II, 21 CFR 870.1250, DQY, QJP
Indications for Use	The APRO 55 Intermediate 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 Intermediate 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.	The APRO 70 Swift 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 70 Swift Catheter is also indicated for use as a conduit for retrieval devices.
Materials			
Hub	Same	Nylon	Nylon
Adhesive	Same	Cyanoacrylate	Cyanoacrylate
Strain Relief	Same	Santoprene (thermoplastic elastomer)	Santoprene (thermoplastic elastomer)
Liner	Same	Polytetrafluoroethylene/ Tecoflex composite	Polytetrafluoroethylene/ Tecoflex composite
Shaft Coil or Braid	Same	304V stainless steel braid 304V stainless steel coil	304V stainless steel braid 304V stainless steel coil
Extrusions	Same	Thermoplastic polyurethanes, thermoplastic elastomer	Thermoplastic polyurethanes, thermoplastic elastomer
Marker Band	Same	Platinum/ iridium	Platinum/ iridium
Coating	Same	Hydrophilic coating	Hydrophilic coating
Dimensions			
Outer Diameter	Same as predicate	0.066 inch	0.083 inch
Inner Diameter	Same as predicate	0.055 inch	0.070 inch
Effective Length	Same as predicate	125, 137 cm	125, 132, 135 cm
Coated Length	Same as predicate	90, 102 cm	90, 97, 100 cm
Tip Shape	Same	Straight	Straight

Table 1. Comparison with the Predicate and Reference Devices			
Category	**Subject Device** **APRO 55 Intermediate Catheter**	**Predicate Device** **APRO 55 Catheter**	**Reference device** **APRO 70 Swift Catheter**
510(k) Number	K250962	K234115	K243297
Accessories			
Introducer Sheath	Same	Yes	Yes
Packaging Materials			
Pouch	Same	Nylon/polyethylene/Tyvek	Nylon/polyethylene/Tyvek
Hoop Coil	Same as reference	Not included	Polyethylene
Packaging Tube	Not included	Polyethylene	Not included
Packaging Card	Same	Polyethylene	Polyethylene
Shelf Carton	Same	Solid bleached sulfate paperboard	Solid bleached sulfate paperboard
Other			
Sterilization	Same	Ethylene oxide	Ethylene oxide
Shelf Life	Same as reference	6 months	1 year
Method of Supply	Same	Sterile and single use	Sterile and single use
Packaging Configuration	Same as reference	The catheter is placed in a polyethylene dispenser tube. The dispenser tube and the introducer sheath are positioned on a polyethylene packaging card, which is then inserted into a Tyvek pouch. The pouch, along with the instructions for use (IFU) is packaged in a bleached sulfate carton box.	The catheter is placed in a coiled polyethylene dispenser tube. The introducer sheath, positioned on a polyethylene packaging card, is attached to the dispenser tube, which is then inserted into a Tyvek pouch. The pouch, along with the IFU is packaged in a bleached sulfate carton box.

Non-Clinical Testing Summary

The following data were provided to evaluate the performance and support the substantial equivalence of the APRO 55 Intermediate Catheter.

Bench Testing

Performance bench testing was not conducted as sterility and shelf-life testing was sufficient for verification and validation of the change in packaging configuration.

Sterility and Shelf-Life

The APRO 55 Intermediate 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 established that the packaging remains functional for the labeled expiration date. Both t=0 and aging studies for packaging integrity and seal strength were performed and met the acceptance criteria.

Biocompatibility

The subject APRO 55 Intermediate Catheter is classified as an externally communicating device with circulating blood contact for a limited duration (≤24 hours) in accordance with ISO 10993-1 and the FDA guidance document, *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices—Part 1: Evaluation and testing within a risk management process."*

The design and manufacturing of the subject device utilize the same materials, processing methods, and sterilization as the predicate device (K234115) and the reference device (K243297), for which Alembic has already conducted biocompatibility testing in compliance with ISO 10993-1. Therefore, no additional biocompatibility testing is required.

Animal Study

An animal study was deemed not necessary to support the substantial equivalence of the subject device.

Clinical Testing Summary

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

Conclusion

Based on the comparison of the technological characteristics and the non-clinical testing described in this 510(k) Summary, 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.