October 30, 2025

Arctx Medical
% Cindy Domecus
Principal
Domecus Consulting Services LLC
1171 Barroilhet Drive
Hillsborough, California 94010

Re: K250632
Trade/Device Name: Arctx Cool Catheter Set
Regulation Number: 21 CFR 870.5910
Regulation Name: Esophageal Thermal Regulation Device
Regulatory Class: Class II
Product Code: PLA
Dated: October 9, 2025
Received: October 9, 2025

Dear Cindy Domecus:

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,

Nicole M. Gillette -S

Nicole Gillette
Assistant Director
DHT2B: Division of Circulatory Support,
Structural, and Vascular Devices
OHT2: Office of Cardiovascular 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)*
K250632

Device Name
Arctx Cool Catheter Set

Indications for Use *(Describe)*
The Arctx Cool Catheter Set is a thermal regulating device, intended to: connect to a Blanketrol III Hyper-Hypothermia System to control patient temperature, allow enteral administration of fluids, and provide gastric decompression and suctioning.

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.

510(k) Summary
K250632

Contact Details

Applicant Name: Arctx Medical, Inc

Applicant Address: 5856 Farington Place, Suite 200 Raleigh, NC 27609 United States
Applicant Contact Telephone: (650) 218-3634
Applicant Contact: Mr. Don Gurskis
Applicant Contact Email: dgurskis@arctxmedical.com

Correspondent Name: Domecus Consulting Services LLC
Correspondent Address: 1171 Barroilhet Drive, Hillsborough, CA 94010 United States
Correspondent Contact Telephone: (650) 773-3445
Correspondent Contact: Mrs. Cindy Domecus
Correspondent Contact Email: cindy@domecusconsulting.com

Device Name

Device Trade Name: Arctx Cool Catheter Set
Common Name: Esophageal thermal regulation device
Classification Name: Esophageal Thermal Regulation And Gastric Suctioning Device
Regulation Number: 21 CFR 870.5910
Product Code: PLA

Legally Marketed Predicate Devices

Predicate Number: K170029
Predicate Trade Name: Esophageal Cooling Device
Predicate Product Code: PLA

Device Description Summary

The ACC Set is comprised of the Arctx Catheter and the Arctx Extension Line.

The ACC Set is intended to cool or warm a patient's temperature for up to 72 hours when connected to a commercial external thermal regulating system, provide gastric decompression and suctioning, and allow enteral administration of fluids. The Arctx Catheter is inserted through the nasopharynx, past the oropharynx and into the esophagus and stomach/duodenum where two lumens deliver cooled or heated water in a closed circuit, from a commercial thermal regulating system to control patient temperature. The circulating water does not contact the patient.

A third catheter lumen enables gastric suction and decompression as well as enteral administration of fluids.

The Arctx Catheter is made of standard medical-grade thermoplastic elastomers. It is a single-use, disposable, non-implantable device. The ACC Set has a quick-connect system that allows the Arctx Catheter to be easily disconnected from the Arctx Extension Line while the catheter remains in place. The quick-connect system allows the patient to move around freely for bathroom breaks, and other medical procedures outside the hospital room. The Arctx Catheter connects to the external thermal regulating system via the Arctx Extension Line.

The ACC Set is intended to be used with the Gentherm Medical Blanketrol III System, model #233. The Blanketrol III System supplies temperature-controlled water through a connector conduit to the ACC Set. An accessory temperature probe interfaces with the Blanketrol and the patient to measure patient temperature, which is displayed on the Blanketrol III System control panel. The Blanketrol III System controls water temperature by mixing hot and cold water using hot and cold solenoid valves under microprocessor control, and includes a circulating pump, heater, and refrigeration system.

Intended Use/Indications for Use

The Arctx Cool Catheter Set is a thermal regulating device, intended to: connect to a Blanketrol III Hyper-Hypothermia System to control patient temperature, allow enteral administration of fluids, and provide gastric decompression and suctioning.

Indications for Use Comparison

The only difference between the subject and predicate Indications for Use is the listed Hyper-Hypothermia System to which the device is connected. The subject and predicate Indications for Use both reference the Blanketrol III Hyper-Hypothermia System, and the predicate also references the Cincinnati Sub-Zero Blanketrol II System. This difference does not alter the intended therapeutic use of the device, nor does it affect the safety and effectiveness of the device relative to the predicate. Both the subject and predicate devices have the same intended use, which is to control body temperature, allow enteral administration of fluids, and provide gastric decompression and suctioning.

Technological Comparison

The subject and predicate devices have the following same technological characteristics:

- The subject and predicate devices have the same method of thermal transfer (i.e., heat transfer between circulating water in the catheters and the patient's tissue)
- The subject and predicate devices include controls for adjusting target temperature with the same accuracy. Both devices use the same external thermal regulating system responsible for adjusting target temperature.
- The subject and predicate devices utilize the same fluid temperature provided by the same thermal regulating system (4 to 42°C).
- The subject and predicate device rely on a commercial temperature probe to provide feedback to the Blanketrol for fluid and patient temperature regulation. The subject and predicate devices are compatible with the same external thermal

regulating system. Both devices use the thermal regulating system as the power source.
- The subject and predicate devices utilize the same number of lumens for circulating heated or cooled temperature fluid and gastric feeding/decompression.

The following technological differences exist between the subject and predicate devices:
- The subject device utilizes a nasogastric insertion method. The predicate device utilizes an orogastric insertion method. This difference does not raise different questions of safety or effectiveness because the orogastric and nasogastric tissues contacted are mucosal membranes, and the subject and predicate devices both contact tissue in the oropharynx, esophagus, and stomach/duodenum.
- The subject device has a smaller insertion diameter than the predicate device. This size difference does not raise different questions of safety or effectiveness because the Arctx Catheter has a similar profile and method of insertion as nasogastric tubes that are commonly used in medical practice. Due to its smaller size, the subject device allows patients to eat and talk with the device in place.
- The subject device has a longer catheter length than the predicate device. This difference does not raise different questions of safety or effectiveness because the subject device catheter includes a marker to identify an insertion depth of 108cm. The predicate device determines insertion length per the patient anatomy, with a maximum insertion length of 75cm. The difference in maximum inserted catheter length does not raise different questions of safety or effectiveness. The subject device has an overall working catheter length similar to commercially marketed nasogastric tubes.
- The subject and predicate devices utilize different materials. This difference does not raise different questions of safety or effectiveness because the subject device materials have a history of safe use in other medical devices, and biocompatibility testing demonstrates that the subject device materials are biocompatible.
- The subject and predicate devices have different shelf-life durations. This difference does not raise different questions of safety or effectiveness because the subject and predicate devices are tested to the same standards, and both have adequate shelf-life for their intended use.

Non-Clinical and/or Clinical Tests Summary & Conclusions

A combination of bench testing (mechanical integrity, testing to determine temperature change rates, testing to demonstrate compatibility with indicated external controller and shelf-life testing), animal, biocompatibility, electrical EMC, product safety and shelf-life/transit testing, and clinical testing was used to demonstrate substantial equivalence to the predicate device; specifically addressing the special controls defined by FDA Product Code: PLA.

Per ISO 10993-1:2018 § B.4.5.3 Biocompatibility evaluation documentation, the Arctx Catheter was tested for biocompatibility. The results demonstrate that the device is non-

cytotoxic, non-sensitizing, a non-irritant, non-toxic (acute and subacute), non-pyrogenic, and non-reactive in a 2-week implantation test. The results support the contact classification of a surface-contacting device with prolonged mucosal membrane contact.

Two preclinical single animal studies were conducted to evaluate the safety and effectiveness of the Arctx Catheter in a porcine model. The studies examined potential pharyngeal, esophageal, gastric, surrounding organ tissue injury, thermoregulatory impact, and overall device function. Temperature monitoring showed that both core body and localized tissue temperatures remained within safe limits. Device performance was also assessed, confirming that the catheter functioned as intended throughout the procedures with no device failures, migration, or unintended tissue interactions. These findings support the overall safety and effectiveness of the Arctx Catheter for its intended indication.

Clinical feasibility testing supports the safety, feasibility, and effectiveness of the subject device. Clinical testing involved twenty-one (21) participants. 61.9% (13/21) of the participants were male, while 38.1% (9/21) of the participants were female. The mean age of participants on the day of the procedure was 48.1 years ± 14.9 SD (min 18.8, max 71.5). The mean weight of participants was 81.0 kg ± 15.2 SD (min 55.3 kg, max 110 kg). Testing assessed performance, effectiveness, safety, and user experience, with objective criteria confirming effectiveness, and safety monitoring identifying no new concerns.

Overall, results demonstrated that the subject device is as safe and effective as the predicate device for its intended use.

The combination of nonclinical and clinical testing demonstrates that the subject device is as safe and as effective as the predicate device for its intended use.