June 27, 2024

Nuvaira, Inc.
John Carline
Sr. Director of Regulatory/Quality
6500 Wedgewood North, Suite 100
Maple Grove, Minnesota 55311

Re: K233357
Trade/Device Name: EsoCool Thermal Regulation Catheter
Regulation Number: 21 CFR 870.5910
Regulation Name: Esophageal Thermal Regulation Device
Regulatory Class: Class II
Product Code: PLA
Dated: May 28, 2024
Received: May 28, 2024

Dear John Carline:

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,

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)*
K233357

Device Name
EsoCool Thermal Regulation Catheter

Indications for Use *(Describe)*
The EsoCool catheter is a thermal regulating device intended to connect to a Gentherm Blanketrol III Hyper-Hypothermia System to control the patient temperature.

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 - EsoCool™ Thermal Regulation Catheter

Contract Details	
Applicant Name and Address:	Nuvaira, Inc. 6500 Wedgwood Road North, Suite 100 Maple Grove, MN 55311 United States
Applicant Contact Information:	John Carline Sr. Director of RA/QA Tel: 763-450-2819 Email: jcarline@nuvaira.com
Device Name	
Device Trade Name:	EsoCool Thermal Regulation Catheter
Common Name:	Esophageal thermal regulation device
Classification Name:	Esophageal thermal regulation device
Regulation Number:	870.5910
Product Code:	PLA
Legally Marketed Predicate Devices	
Predicate Number:	K172493
Predicate Trade Name:	EnsoETM
Predicate Product Code:	PLA
Device Description Summary:	
The EsoCool Thermal Regulation Catheter is a dual lumen tube that is placed in the esophagus. The two lumens are connected to an external heater cooler to allow for circulation of cold or warm fluid in a closed loop system. Heater cooler control is used to modulate the fluid temperature and control of patient's temperature. The EsoCool catheter is made of polyurethane with barium sulfate for radiopacity. The EsoCool catheter is a single-use, disposable, non-implantable device with an intended duration of use of 24 hours or less.	
Intended Use/Indications for Use:	
The EsoCool catheter is a thermal regulating device intended to connect to a Gentherm Blanketrol III Hyper-Hypothermia System to control the patient temperature.	
Indications for Use Comparison to Predicate Device:	
Indications for use is the same as the predicate device in that both are intended to control the patient temperature. The EsoCool catheter does not incorporate the optional mechanism for gastric decompression and suctioning and as such does include the indications statement related to gastric decompression and suctioning.	

510(k) Summary - EsoCool™ Thermal Regulation Catheter

Technological Comparison to Predicate Device:
Technological characteristics are the same in that both provide a dual lumen tube to an external heater cooler for circulation of fluid in closed loop system. One difference is that the outer lumen of the EsoCool catheter is radiopaque. Radiopacity of catheters is common across many cardiovascular catheters and does not constitute a novel technological characteristic.
Non-Clinical and/or Clinical Tests Summary and Conclusions:
Bench and animal testing was performed to confirm conformance to the special controls per 21 CFR 870.5910. <u>Bench testing included:</u> 1. Mechanical integrity testing, 2. Compatibility with the designated external heater cooler, and 3. Product stability through the designated shelf-life. <u>Animal testing included:</u> 1. Temperature change rate in the porcine animal model, 2. Gross and light microscopy assessment of the esophagus to demonstrate no esophageal injury, and 3. Temperature profile to demonstrate appropriate boundaries of body temperature in the porcine animal model. In conclusion, non-clinical testing demonstrate that the device is safe and as effective as the legally marked predicate device as identified above.