May 17, 2018

Advanced Cooling Therapy, Inc. d/b/a Attune Medical
Erik Kulstad
Chief Medical Officer
3440 S. Dearborn St.
#215-South
Chicago, Illinois 60616

Re: K180742
Trade/Device Name: EnsoETM
Regulation Number: 21 CFR 870.5910
Regulation Name: Esophageal Thermal Regulation Device
Regulatory Class: Class II
Product Code: PLA
Dated: March 20, 2018
Received: March 22, 2018

Dear Erik Kulstad:

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 (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. 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.

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 803); good

manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 G. Ibrahim -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180742

Device Name
EnsoETM

Indications for Use *(Describe)*

Model # ECD05-A:

The EnsoETM is a thermal regulating device, intended to:

- connect to a Cincinnati Sub-Zero Norm-O-Temp Hyperthermia System to raise or maintain a patient's temperature,
- allow enteral administration of fluids, and
- provide gastric decompression and suctioning.

Model # ECD06-A

The EnsoETM is a thermal regulating device, intended to:

- connect to a Cincinnati Sub-Zero Norm-O-Temp Hyperthermia System to raise or maintain a patient's temperature, 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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SECTION 5: 510(k) Summary of Safety and Effectiveness (21 CFR § 807.92)

Submitter / 510(k) Holder

Company:	Advanced Cooling Therapy, Inc. d/b/a Attune Medical
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Phone:	+1-312-725-4756
Contact Person:	Erik Kulstad
	Chief Medical Officer
Date Prepared:	March 20, 2018

Device Name & Classification

Trade Name:	EnsoETM
Model Number(s):	ECD05-A, ECD06-A
Classification Name:	Esophageal Thermal Regulation Device (21 CFR 870.5910)
Product Code:	PLA
Class:	II

Predicate Device

1. Attune Medical EnsoETM (model #: ECD04-A); K180244
2. Attune Medical EnsoETM (model #: ECD02-A); K172493

Device Description

The EnsoETM is a multi-lumen silicone tube that is placed in the esophagus in a similar manner to a standard orogastric tube to raise or maintain a patient's temperature, while simultaneously maintaining access to the stomach to allow gastric decompression, drainage, and enteral administration of fluids, thereby maintaining the functionality of the standard orogastric tube. Raising or maintaining patient temperature is achieved by connecting the device to an external heat exchanger. Two lumens connect to the external heat exchanger. A third central lumen connects to wall suction to allow standard gastric decompression or, in some models, an enteral administration system to allow enteral administration of fluids. The device is made of standard medical-grade silicone. It is a single-use, disposable, non-implantable device with a duration of use of 72 hours or less.

Indications for Use (Subject Device 1; Model #: ECD05-A)

The EnsoETM is a thermal regulating device, intended to:

- connect to a Cincinnati Sub-Zero Norm-O-Temp Hyperthermia System to raise or maintain a patient's temperature,
- allow enteral administration of fluids, and
- provide gastric decompression and suctioning.

Indications for Use (Subject Device 2; Model #: ECD06-A)

The EnsoETM is a thermal regulating device, intended to:

- connect to Cincinnati Sub-Zero Norm-O-Temp Hyperthermia System to raise or maintain a patient's temperature, and
- provide gastric decompression and suctioning.

Technological Characteristics

The indications for use have been modified to (1) list the Cincinnati Sub-Zero Norm-O-Temp Hyperthermia System as a compatible external heat exchanger instead of the Cincinnati Sub-Zero Blanketrol II or Blanketrol III Hyper-Hypothermia System, and (2) state that the device can only raise or maintain a patient's temperature instead of controlling (i.e. raising, maintaining, or lowering) it.

All other technological characteristics (including principles of operation, materials, and design) remain identical. The Cincinnati Sub-Zero Norm-O-Temp Hyperthermia System provides functionality and safety features comparable to the Cincinnati Sub-Zero Blanketrol II or Blanketrol III Hyper-Hypothermia System.

Non-Clinical Performance Testing

Non-clinical performance testing was conducted to demonstrate the compatibility of the device with the Cincinnati Sub-Zero Norm-O-Temp Hyperthermia System. The following tests were performed:

Test performed	Discussion
Coolant lumen flow rate	Coolant lumen flow rate testing demonstrated the EnsoETM is suitable for maintaining thermal transfer capabilities.

Conclusion

The results of all performance testing demonstrated the subject devices are substantially equivalent to the predicate devices.