February 28, 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: K180244
Trade/Device Name: EnsoETM
Regulation Number: 21 CFR 870.5910
Regulation Name: Esophageal Thermal Regulation Device
Regulatory Class: Class II
Product Code: PLA
Dated: January 26, 2018
Received: January 29, 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)*
K180244

Device Name
EnsoETM

Indications for Use *(Describe)*
Model # ECD03-A:
The EnsoETM is a thermal regulating device, intended to:
• connect to a Gaymar Medi-Therm III Conductive Hyper/Hypothermia System or Stryker Altrix Precision Temperature Management System to control patient temperature,
• allow enteral administration of fluids,
• and provide gastric decompression and suctioning.

Model # ECD04-A:
The EnsoETM is a thermal regulating device, intended to:
• connect to a Cincinnati Sub-Zero Blanketrol II or 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.

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

Submitter / 510(k) Holder

Company:	Advanced Cooling Therapy, Inc. d/b/a Attune Medical
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	Chicago, IL 60616
Phone:	+1-708-651-0736
Contact Person:	Erik Kulstad
	Chief Medical Officer
Date Prepared:	January 26, 2018

Device Name & Classification

Trade Name:	EnsoETM
Model Number(s):	ECD03-A, ECD04-A
Classification Name:	Esophageal Thermal Regulation Device (21 CFR 870.5910)
Product Code:	PLA
Class:	II

Predicate Devices

Attune Medical EnsoETM (model #s: ECD03-A & ECD04-A); K172029

Reference Devices

Attune Medical EnsoETM (model #s: ECD01-A & 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 control 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. Modulation and control of 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 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 #: ECD03-A)

The EnsoETM is a thermal regulating device, intended to:

- connect to a Gaymar Medi-Therm III Conductive Hyper/Hypothermia System or Stryker Altrix Precision Temperature Management System to control patient temperature,
- allow enteral administration of fluids, and

- provide gastric decompression and suctioning.

Indications for Use (Subject Device 2; Model #: ECD02-A)

The EnsoETM is a thermal regulating device, intended to:

- connect to a Cincinnati Sub-Zero Blanketrol II or Blanketrol III Hyper-Hypothermia System to control patient temperature,
- allow enteral administration of fluids, and
- provide gastric decompression and suctioning.

Technological Characteristics

The EnsoETM product family currently consists of four models:

- the ECD03-A (Predicate Device 1 cleared under K172029),
- the ECD04-A (Predicate Device 2 cleared under K172029),
- the ECD01-A (Reference Device 1 cleared under K172493), and
- the ECD02-A (Reference Device 2 cleared under K172493).

The purpose of this Special 510(k) submission is to increase the duration of use for the ECD03-A and ECD04-A models from 36 hours to 72 hours. The subject devices are identical to the predicate devices except for the change to the duration of use.

The subject devices have the same duration of use as the reference devices and are identical to the reference devices except for the gastric lumen connector and the inclusion of enteral administration of fluids in the indication statement.

Table 1 details the differences between the subject, predicate, and reference devices. Device characteristics not described in Table 2 are identical for all devices.

Table 1: Differences Between EnsoETM Models

Model #	Coolant Lumen Fittings	Gastric Lumen Fittings	Intended heat exchanger	Enteral administration of fluids?	Duration of use
ECD03-A (Predicate Device 1)	Clik-Tite connectors	Male ENFit connector	Stryker/Gaymar Medi-Therm III or Stryker Altrix	Yes	36 hours
ECD04-A (Predicate Device 2)	Colder PLC series connectors	Male ENFit connector	Cincinnati Sub-Zero Blanketrol II or Blanketrol III	Yes	36 hours
ECD01-A (Reference Device 1)	Clik-Tite connectors	5° silicone taper	Stryker/Gaymar Medi-Therm III or Stryker Altrix	No	72 hours
ECD02-A (Reference Device 2)	Colder PLC series connectors	5° silicone taper	Cincinnati Sub-Zero Blanketrol II or Blanketrol III	No	72 hours

Model #	Coolant Lumen Fittings	Gastric Lumen Fittings	Intended heat exchanger	Enteral administration of fluids?	Duration of use
ECD03-A (Subject Device 1)	Clik-Tite connectors	Male ENFit connector	Stryker/Gaymar Medi-Therm III or Stryker Altrix	Yes	72 hours
ECD04-A (Subject Device 2)	Colder PLC series connectors	Male ENFit connector	Cincinnati Sub-Zero Blanketrol II or Blanketrol III	Yes	72 hours

Performance Testing

No additional performance testing was conducted.

Conclusion

Existing data demonstrate Subject Device 1 and Subject Device 2 are substantially equivalent to Predicate Device 1 and Predicate Device 2 respectively.