October 17, 2017

Attune Medical
Erik Kulstad
President/CEO
3440 S. Dearborn St. #215-South
Chicago, Illinois 60616

Re: K172493
Trade/Device Name: EnsoETM
Regulation Number: 21 CFR 870.5910
Regulation Name: Esophageal Thermal Regulation Device
Regulatory Class: Class II
Product Code: PLA
Dated: August 16, 2017
Received: August 18, 2017

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K172493

Device Name
EnsoETM

Indications for Use *(Describe)*
Model #ECD01-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,
• and provide gastric decompression and suctioning.

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,
• 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:	Attune Medical
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	#215-South
	Chicago, IL 60616
Phone:	+1-312-725-4756
Contact Person:	Erik Kulstad
	CEO/President
Date Prepared:	August 16, 2017

Device Name & Classification

Trade Name:	EnsoETM
Model Number(s):	ECD01-A, ECD02-A
Classification Name:	Esophageal Thermal Regulation Device (21 CFR 870.5910)
Product Code:	PLA
Class:	II

Predicate Device

1. Attune Medical EnsoETM (model #: ECD01-A); K170009
2. Attune Medical EnsoETM (model #: ECD02-A); K152450

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 modulate a patient's temperature, while simultaneously maintaining access to the stomach to allow gastric decompression and drainage, thereby maintaining the functionality of the standard orogastric tube. Modulation and control of patient temperature is achieved by connecting the EnsoETM to an external heat exchanger. Two lumens connect to the external heat exchanger. A third central lumen connects to wall suction and is used for standard gastric decompression. The EnsoETM is made of standard medical-grade silicone. It is a single-use, disposable, non-implantable device with an intended duration of use of 72 hours or less.

Indications for Use (Subject Device 1; Model #: ECD01-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,
- 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, and
- provide gastric decompression and suctioning.

Technological Characteristics

The EnsoETM product family currently consists of two models: the ECD01-A (Predicate Device 1 cleared under K170009) and ECD02-A (Predicate Device 2 cleared under K152450). The purpose of this 510(k) submission is to increase the intended duration of use for the EnsoETM product family from 36 hours to 72 hours. Table 1 describes the differences between the predicate and subject devices. Device characteristics not described in Table 1 are identical for all devices.

Table 1: Differences between EnsoETM models

Model #	Coolant Lumen Fittings	Intended Heat Exchanger	Intended Duration of Use
ECD01-A (Predicate Device 1)	Clik-Tite connectors	Stryker/Gaymar Medi-Therm III or Stryker Altrix	36 hours
ECD02-A (Predicate Device 2)	Colder PLC series connectors	Cincinnati Sub-Zero Blanketrol II or Blanketrol III	36 hours
ECD01-A (Subject Device 1)	Clik-Tite connectors	Stryker/Gaymar Medi-Therm III or Stryker Altrix	72 hours
ECD02-A (Subject Device 2)	Colder PLC series connectors	Cincinnati Sub-Zero Blanketrol II or Blanketrol III	72 hours

Subject Device 1 has the identical technological characteristics (including indications for use, patient population, principles of operation, materials, and design) as Predicate Device 1. The only difference is the increase in the intended duration of use from 36 hours to 72 hours.

Subject Device 2 has the technological characteristics (including indications for use, patient population, principles of operation, materials, and design) as Predicate Device 2. The only difference is the increase in the intended duration of use from 36 hours to 72 hours.

Performance Testing

A retrospective analysis of real-world human use data was conducted to demonstrate the subject devices are safe and effective for an intended duration of use of 72 hours by analyzing real-world human clinical data from 18 patients.

Conclusion

The results of all testing and data analysis demonstrate Subject Device 1 and Subject Device 2 are substantially equivalent to Predicate Device 1 and Predicate Device 2 respectively.