January 5, 2018

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

Re: K172029
Trade/Device Name: EnsoETM, Models ECD03-A and ECD04-A
Regulation Number: 21 CFR 870.5910
Regulation Name: Esophageal Thermal Regulation Device
Regulatory Class: Class II
Product Code: PLA
Dated: December 1, 2017
Received: December 5, 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.

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

SECTION 4: Indications for Use Statement

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)*

K172029

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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Summary of Safety and Effectiveness

Submitter / 510(k) Holder

Company:	Attune Medical
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Phone:	+1-312-725-4756
Contact Person:	Erik Kulstad
	CEO/President

Date Prepared:	June 30, 2017

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

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

Reference Device

1. Maquet Critical Care Ab Edi Catheter ENFit; K153688

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 an intended duration of use of 36 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 #: 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.

Technological Characteristics

The EnsoETM product family consists of four distinct models: the ECD01-A (Predicate Device 1 cleared under K170009), ECD02-A (Predicate Device 2 cleared under K152450), ECD03-A (Subject Device 1), and ECD04-A (Subject Device 2). Table 1 describes the differences between the four models. Device characteristics not described in Table 1 are identical for all models.

Table 1: Differences between EnsoETM models

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

Non-Clinical Performance Testing

Non-clinical performance testing was conducted to demonstrate the technological characteristics of the subject devices are substantially equivalent to the predicate devices. The following tests were performed:

Test performed	Discussion
Tensile force	Tensile force testing demonstrated the ENFit connector and ENFit connector joint on the subject devices are suitable for use, including insertion into and removal from the esophagus.
Gastric lumen burst strength	Gastric lumen burst strength testing demonstrated the gastric lumen of the subject devices can withstand the operating pressures supplied by an enteral administration system.
Gastric lumen leakage	Gastric lumen leakage testing demonstrated the gastric lumen, gastric lumen connector, and gastric lumen connector joint of the subject devices do not allow enterally administered fluids to escape the gastric lumen.
Gastric lumen flow rate	Gastric lumen flow rate testing demonstrated the gastric lumen of the subject devices is capable of providing flow of fluids representative of those clinically used for enteral feeding in acute care facilities.
Resistance to vacuum	Resistance to vacuum testing demonstrated the subject devices are capable of performing gastric decompression and suctioning.
Positive pressure leakage	Positive pressure liquid leakage testing demonstrated the ENFit connector does not leak fluid while under pressure.
Leakage by pressure decay	Leakage by pressure decay testing demonstrated the ENFit connector does not leak fluid while under pressure.
Stress cracking	Stress cracking testing demonstrated the ENFit connector does not fail when subjected to typical use-case stresses.
Resistance to separation from axial load	Resistance to separation from axial load testing demonstrated the ENFit connector does not inadvertently separate when subjected to typical use-case axial loads.
Resistance to separation from unscrewing	Resistance to separation from unscrewing testing demonstrate the ENFit connector does not inadvertently separate when subjected to typical use-case torques.
Resistance to overriding	Resistance to overriding testing demonstrated the ENFit connector does not override the threads when subjected to typical use-case torques.
Disconnection by unscrewing	Disconnection by unscrewing demonstrated the ENFit connector is capable of being disconnected by the end user with a reasonable amount of torque.
Dimensional verification	Dimensional verification demonstrated the dimensions of the ENFit connector satisfy the dimensional requirements of ISO 80369-3:2016.
Flexural modulus	Flexural modulus verification demonstrated the material used to manufacture the ENFit connector satisfies the flexural modulus requirements of ISO 80369-3:2016.

Conclusion

The results of all performance testing demonstrate the subject devices have technological characteristics that do not raise new questions of safety or effectiveness when compared to the predicate devices. Therefore, the subject devices are substantially equivalent to the predicate devices.