DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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June 23, 2015

Advanced Cooling Therapy, LLC
Erik Kulstad
President
3440 S. Dearborn St. #215-South
Chicago, IL 60616

Re: DEN140018
Esophageal Cooling Device
Evaluation of Automatic Class III Designation – *De Novo* Request
Regulation Number: 21 CFR 870.5910
Regulation Name: Esophageal Thermal Regulation Device
Regulatory Classification: Class II
Product Code: PLA
Dated: May 8, 2014
Received: May 9, 2014

Dear Erik Kulstad:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your *de novo* request for classification of the Esophageal Cooling Device, a prescription device under 21 CFR Part 801.109 with the following indication:

"*The Esophageal Cooling Device is a thermal regulating device, intended to:*
- *connect to a Gaymar Medi-Therm III Conductive Hyper/Hypothermia System to control patient temperature, and*
- *provide gastric decompression and suctioning.*"

FDA concludes that this device should be classified into class II. This order, therefore, classifies the Esophageal Cooling Device, and substantially equivalent devices of this generic type, into class II under the generic name, esophageal thermal regulation device.

FDA identifies this generic type of device:

> **Esophageal thermal regulation device.** An esophageal thermal regulation device is a prescription device used to apply a specified temperature to the endoluminal surface of the esophagus via an external controller. This device may incorporate a mechanism for gastric decompression and suctioning. The device is used to regulate patient temperature.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This new law provides two options for *de novo* classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been

previously classified under the Act may, within 30 days of receiving notice of the NSE determination, request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** classifying the device type.

On May 9, 2014, FDA received your *de novo* requesting classification of the Esophageal Cooling Device into class II. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Esophageal Cooling Device into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

After review of the information submitted in the *de novo* request, FDA has determined that the Esophageal Cooling Device indicated for:

"The Esophageal Cooling Device is a thermal regulating device, intended to:

- *connect to a Gaymar Medi-Therm III Conductive Hyper/Hypothermia System to control patient temperature, and*
- *provide gastric decompression and suctioning."*

can be classified in class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in Table 1.

Table 1 – Identified Risks to Health and Mitigation Measures

Identified Risk	**Mitigation Measure**
Adverse Tissue Reaction	Biocompatibility Testing
Gastric Distension	Non-clinical Performance Evaluation Labeling
Injury to the Esophagus	Non-clinical Performance Evaluation Animal Testing Labeling
Harmful Hypo/Hyperthermia	Non-clinical Performance Evaluation Animal Testing Labeling
Injury to the Trachea	Labeling

In combination with the general controls of the FD&C Act, the esophageal thermal regulation device is subject to the following special controls:

1. The patient contacting materials must be demonstrated to be biocompatible.
2. Non-clinical performance evaluation must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:

   a. Mechanical integrity testing
   b. Testing to determine temperature change rate(s)
   c. Testing to demonstrate compatibility with the indicated external controller
   d. Shelf life testing
3. Animal testing must demonstrate that the device does not cause esophageal injury and that body temperature remains within appropriate boundaries under anticipated conditions of use.
4. Labeling must include the following:
   a. Detailed insertion instructions
   b. Warning against attaching device to unintended connections, such as external controllers for which the device is not indicated or pressurized air outlets instead of vacuum outlets for those devices including gastric suction
   c. The operating parameters, name, and model number of the indicated external controller
   d. The intended duration of use.

In addition, this is a prescription device and must comply with 21 CFR 801.109. Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the esophageal thermal regulation device they intend to market prior to marketing the device and receive clearance to market from FDA.

Please be advised that FDA's decision to grant this *de novo* request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD & C 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 FD & C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the **Federal Register**. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the *de novo* request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact Lydia Glaw at (301) 796-1456.

Sincerely yours,

Jonette R. Foy -S

Jonette Foy, Ph.D.
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