DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 16, 2016

Acclarent, Inc.
James Patrick Garvey II
Associate Director, Regulatory Affairs
33 Technology Drive
Irvine, CA 92618

Re: DEN150056
ACCLARENT AERA™ Eustachian Tube Balloon Dilation System
Evaluation of Automatic Class III Designation – *De Novo* Request
Regulation Number: 21 CFR 874.4180
Regulation Name: Eustachian Tube Balloon Dilation System
Regulatory Classification: Class II
Product Code: PNZ
Dated: December 4, 2015
Received: December 17, 2015

Dear Mr. Garvey:

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 ACCLARENT AERA™ Eustachian Tube Balloon Dilation System, a prescription device under 21 CFR Part 801.109 that is *indicated to dilate the Eustachian tube for treatment of persistent Eustachian tube dysfunction in adults ages 22 and older*. FDA concludes that this device should be classified into class II. This order, therefore, classifies the ACCLARENT AERA™ Eustachian Tube Balloon Dilation System, and substantially equivalent devices of this generic type, into class II under the generic name, Eustachian Tube Balloon Dilation System.

FDA identifies this generic type of device as:

> **Eustachian Tube Balloon Dilation System**. A Eustachian tube balloon dilation system is a prescription device that includes a flexible catheter attached to an inflatable balloon. The system is intended for use in dilating the cartilaginous portion of the Eustachian tube for treating persistent Eustachian tube dysfunction.

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 December 17, 2015, FDA received your *de novo* requesting classification of the ACCLARENT AERA™ Eustachian Tube Balloon Dilation System into class II. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the ACCLARENT AERA™ Eustachian Tube Balloon Dilation System 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 and during interactive review**,** FDA has determined that the ACCLARENT AERA™ Eustachian Tube Balloon Dilation System, *indicated to dilate the Eustachian tube for treatment of persistent Eustachian tube dysfunction in adults ages 22 and older*, can be classified in class II with the establishment of special controls for 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**
Introduction of false passages and rupture or damage to carotid artery	Non-clinical performance testing Simulated use testing Training Labeling
Injury to mucosal tissue • due to misuse of device on patulous Eustachian tube or following skull base surgery • due to catheter mechanical failure • due to balloon rupture • due to mishandling of device with respect to excessive force and/or incorrect positioning	Non-clinical performance testing Simulated use testing Shelf life validation Training Labeling
Adverse tissue reaction	Biocompatibility evaluation
Infection	Sterilization validation Shelf life validation Labeling

In combination with the general controls of the FD&C Act, the Eustachian Tube Balloon Dilation System is subject to the following special controls:

1. Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be evaluated:

   a. Mechanical testing, including tensile and flexural testing of catheter joints and materials.
   b. Durability testing, including fatigue and burst pressure testing of the balloon materials and components.
   c. Inflation and deflation characterization testing, including time and pressure measurements, and leak testing of the balloon.
   d. Verification testing of safety features built into the device must be performed, including the characterization of catheter geometries and distal tip insertion limitation mechanisms.

2. Simulated use testing in a clinically relevant model must demonstrate the reliability of the device to remain mechanically functional throughout the anticipated conditions of use, and validate that the design features limit access to only the cartilaginous portion of the Eustachian tube.

3. The patient-contacting components of the device must be demonstrated to be biocompatible.

4. Performance data must demonstrate the sterility of the device.

5. Performance data must support shelf life by demonstrating continued sterility of the device, package integrity and device functionality over the identified shelf life.

6. Training must include simulated use on cadavers to ensure users can follow the instructions for use to allow safe use of the device.

7. Labeling must include:
   a. Detailed instructions for use.
   b. A detailed summary of the device technical parameters, including maximum allowed inflation pressure, allowable catheter geometries, and available balloon sizes.
   c. A shelf life.

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 Eustachian Tube Balloon Dilation System 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 Joyce Lin, Ph.D. at 301-796-5620.

Sincerely,

Jonette R. Foy -S

Jonette Foy, Ph.D.
Deputy Director
for Engineering and Science Review
Office of Device Evaluation
Center for Devices and
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