DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 29, 2015

EarLens Corporation
c/o Deborah Arthur
Regulatory Consultant to EarLens Corporation
231 Queens Road
Charlotte, NC 28204

Re: DEN150002
EarLens™ Contact Hearing Device
Evaluation of Automatic Class III Designation – *De Novo* Request
Regulation Number: 874.3315
Regulation Name: Tympanic membrane contact hearing aid
Regulatory Classification: Class II
Product Code: PLK
Dated: January 5, 2015
Received: January 6, 2015

Dear Ms. Arthur:

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 EarLens™ Contact Hearing Device, a prescription device under 21 CFR Part 801.109. *The EarLens™ Contact Hearing Device transmits amplified sound by vibrating the eardrum through direct contact. It is indicated for individuals 18 years and older with a mild to severe sensorineural hearing impairment who can benefit from amplification. The device can provide the full spectrum of amplification that includes 125 Hz – 10,000 Hz.* FDA concludes that this device should be classified into class II. This order, therefore, classifies the EarLens™ Contact Hearing Device, and substantially equivalent devices of this generic type, into class II under the generic name, tympanic membrane contact hearing aid.

FDA identifies this generic type of device as:

> **Tympanic membrane contact hearing aid:** A tympanic membrane contact hearing aid is a prescription device that compensates for impaired hearing. Amplified sound is transmitted by vibrating the tympanic membrane through a transducer that is in direct contact with the tympanic membrane.

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 January 6, 2015, FDA received your *de novo* requesting classification of the EarLens™ Contact Hearing Device into class II. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the EarLens™ Contact Hearing 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 EarLens™ Contact Hearing Device, with the following indications for use, can be classified in class II with the establishment of special controls for class II: "EarLens™ Contact Hearing Device transmits amplified sound by vibrating the eardrum through direct contact. It is indicated for individuals 18 years and older with a mild to severe sensorineural hearing impairment who can benefit from amplification. The device can provide the full spectrum of amplification that includes 125 Hz – 10,000 Hz." FDA believes 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 Method**
Adverse Tissue Reactions	• Biocompatibility • Labeling
Electromagnetic Incompatibility	• Non-Clinical Performance Testing • Labeling
MRI Incompatibility	• Labeling
Overheating of Ear Canal or Skin	• Non-Clinical Performance Testing • Clinical Performance Testing • Labeling
Damage to Eyes from Direct Laser Exposure	• Labeling
Trauma/Damage to the Ear Canal, Tympanic Membrane, or Middle Ear System	• Non-Clinical Performance Testing • Clinical Performance Testing • Training • Labeling

Residual Hearing Loss	• Non-Clinical Performance Testing • Clinical Performance Testing • Labeling
Ear Infections	• Clinical Performance Testing • Labeling
Vertigo or Tinnitus	• Clinical Performance Testing • Labeling
Dampening of Residual Hearing When the Device Is Turned off	• Clinical Performance Testing • Labeling

In combination with the general controls of the FD&C Act, the tympanic membrane contact hearing aid is subject to the following special controls:

1. The patient contacting components must be demonstrated to be biocompatible.

2. Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use, and must include:

   (A) Mechanical integrity testing.
   (B) Electrical and thermal safety testing.
   (C) Software verification, validation, and hazard analysis.
   (D) Reliability testing consistent with expected device life.
   (E) Electromagnetic compatibility testing.
   (F) Validation testing of device output and mechanical forced applied to the tympanic membrane in a clinically appropriate model.

3. Clinical performance testing must characterize any adverse events observed during clinical use, and demonstrate that the device performs as intended under anticipated conditions of use.

4. Professional training must include the ear impression procedure, correct placement, fitting, monitoring, care, and maintenance of the device.

5. Labeling must include the following:

   (A) A detailed summary of the adverse events and effectiveness outcomes from the clinical performance testing.
   (B) Detailed instructions on how to fit the device to the patient.
   (C) Instructions for periodic cleaning of any reusable components.
   (D) Information related to electromagnetic compatibility.
   (E) Patient labeling that includes:
      (i) A patient card that identifies if a patient has been fitted with any non-self-removable components of the device and provides relevant information in cases of emergency.

(ii) Information on how to correctly use and maintain the device.
(iii) The potential risks and benefits associated with the use of the device.
(iv) Alternative treatments.

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 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 tympanic membrane contact hearing aid 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 Cherish Giusto, AuD at 301-796-9679.

Sincerely,

Jonette R. Foy -S

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