January 25, 2019

Earlens Corporation
Judith Brimacombe, M.A.
Vice President, Clinical & Regulatory Affairs
4045 Campbell Avenue
Menlo Park, CA 94025

Re: K182480
Trade/Device Name: Earlens Contact Hearing Aid
Regulation Number: 21 CFR 874.3315
Regulation Name: Tympanic Membrane Contact Hearing Aid
Regulatory Class: Class II
Product Code: PLK
Dated: December 21, 2018
Received: December 26, 2018

Dear Judith Brimacombe:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 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 yours,

Srinivas Nandkumar -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)* K182480

Device Name
Earlens Contact Hearing Aid

Indications for Use *(Describe)*

The Earlens Contact Hearing Aid 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.

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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510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

APPLICANT:	Earlens Corporation
ADDRESS:	4045 Campbell Avenue, Menlo Park, CA 94025
TELEPHONE & FAX:	(650) 366-9000 (TELEPHONE); (650) 397-4426 (FAX)
CONTACT PERSON:	Judith A. Brimacombe

TRADE NAME:	Earlens Contact Hearing Aid
COMMON NAME:	Earlens Hearing Aid
CLASSIFICATION NAME:	Tympanic Membrane Contact Hearing Aid
DEVICE CLASSIFICATION:	21 CFR874.3315
PRODUCT CODE:	PLK
PREDICATE DEVICE:	Wireless Earlens Light Driven Hearing Aid (K153634)
DATE PREPARED:	September 6, 2018

INTENDED USE:

The Earlens Contact Hearing Aid is intended to compensate for impaired hearing by transmitting sound vibrations through direct contact (mechanical vibration) to the tympanic membrane (eardrum).

INDICATIONS FOR USE:

The Earlens Contact Hearing Aid 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.

DEVICE DESCRIPTION:

The Earlens Hearing Aid consists of several components including a Processor worn behind the pinna, an Ear Tip that is placed in the external ear canal, and a Tympanic Lens that is placed in the anterior sulcus near the tympanic membrane. Sound waves are received by the two directional microphones on the Processor and converted into electrical signals, digitally processed, amplified and sent to the Ear Tip through a cable. The Ear Tip houses a transmit coil, which converts the electrical signal containing the amplified sound into electromagnetic energy. This energy is transmitted to a receive coil on the Tympanic Lens. Both data and

power are sent from the transmit coil to the receive coil by resonant inductive coupling. The receive coil converts the electromagnetic energy back into electrical signals, thereby activating the microactuator of the Tympanic Lens to transmit sound vibrations to the umbo.

The Tympanic Lens is placed deep in the ear canal and adjacent to the tympanic membrane by a trained ENT physician through a non-invasive and non-surgical procedure. The Tympanic Lens makes contact with the umbo of the tympanic membrane and is intended to remain in the ear for greater than 30 days.

An Audiologist uses the Earlens Fitting software (ELF) to prescribe the gain and overall output of the Processor based on the recipient's hearing profile.

A Charger is provided to the recipient to recharge the Lithium-Ion battery of the Processor daily.

SUBSTANTIAL EQUIVALENCE:

The Earlens Contact Hearing Aid has the same intended use and fundamental scientific technology as the predicate, the Wireless Earlens Light Driven Hearing Aid (K153634). In the same manner as its predicate, the Earlens Contact Hearing Aid directly vibrates the umbo of the tympanic membrane to transmit sound to the recipient. The modification to the Earlens Contact Hearing Aid involves the replacement of the infrared light link used to transmit power and data from the Ear Tip to the Tympanic Lens with a new method, resonant inductive coupling. Specifically, the laser emitter in the Ear Tip is being replaced with a parylene encapsulated transmit coil and the photodetector on the Tympanic Lens is being replaced with a parylene encapsulated receive coil. The inductive system does not require line of sight to ensure that the signal and power are transmitted, as is the case with the infrared light link. Therefore, the signal transmission with the inductive system is less affected by normal jaw movements when individuals smile or chew.

All other components and mechanisms of action remain the same as those described in K153634 for the Wireless Earlens Light Driven Hearing Aid. The Earlens Contact Hearing Aid offers the same wireless connectivity to the user as the predicate, the Wireless Earlens Light Driven Hearing Aid. With this feature, the user can stream telephone calls, music, and other media from a cell phone or other mobile device directly to the Earlens Contact Hearing Aid via a Bluetooth low energy protocol.

NON-CLINICAL PERFORMANCE TESTING:

Electrical safety and electromagnetic compatibility (EMC) were evaluated and the Earlens Contact Hearing Aid was found to be in compliance with IEC 60601-1:2005, IEC 60601-1-2:2014, IEC 60601-1-6:2013, and IEC 60601-1-11:2015.

The modified Earlens device has the same patient contacting materials as the predicate device, the Wireless Earlens Light Driven Hearing Aid (K153634). Biocompatibility was evaluated and the Earlens Contact Hearing Aid was found to be in compliance with ISO 10993-1:2009, ISO 10993-5:2009, ISO 10993-10:2010, and ISO 10993-12:2012.

In addition to the biocompatibility, electrical safety, and electromagnetic compatibility testing, Earlens completed mechanical integrity testing, thermal testing, acoustic safety and performance testing, environmental conditioning and transit validation testing, one year accelerated life testing, and software verification testing on the Earlens Contact Hearing Aid and its respective components in accordance with predetermined acceptance criteria to provide a reasonable assurance of safety and effectiveness. The test results demonstrated that Earlens Contact Hearing Aid passed all the acceptance criteria and is substantially equivalent to the Wireless Earlens Light Driven Hearing Aid (K153634).

CLINICAL PERFORMANCE TESTING:

Thirty subjects were enrolled in a human factors study to assess whether sound variability would be reduced and maximum equivalent pressure output maintained by wearers of the Earlens Light-Driven Hearing Aid when they were refitted with an Earlens Contact Hearing Aid with resonant inductive coupling. Assessments included maximum equivalent pressure output (MEPO), aided sound field thresholds, aided word recognition, and subjective questionnaires. On average, MEPO was higher and less variable for the Inductive system (108 dB for the light-based system and 115 dB for the Inductive system) but still within safe and effective limits for the intended population. Aided sound field thresholds were very similar for the two systems and demonstrated that Earlens wearers were receiving amplification through 10 kHz. Subjective reports of sound variability were all but eliminated with use of the Inductive system as compared to the light-based system. These clinical findings support the substantial equivalence of the Earlens Contact Hearing Aid with resonant inductive coupling to the Earlens Light-Driven Hearing Aid.

CONCLUSION:

The Earlens Contact Hearing Aid is substantially equivalent in intended use and fundamental scientific technology to the Wireless Earlens Light Driven Hearing Aid. The Earlens Contact Hearing Aid is safe and effective for its intended use when used in accordance with its Instructions for Use.