

**DE NOVO CLASSIFICATION REQUEST FOR  
EARLENS™ CONTACT HEARING DEVICE (CHD)**

**REGULATORY INFORMATION**

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.

**NEW REGULATION NUMBER: 874.3315**

**CLASSIFICATION: CLASS II**

**PRODUCT CODE: PLK**

**BACKGROUND**

**DEVICE NAME: EARLENS™ CONTACT HEARING DEVICE (CHD)**

**SUBMISSION NUMBER: DEN150002**

**DATE OF DE NOVO: JANUARY 6, 2015**

**CONTACT: EARLENS™ CORPORATION  
4045A CAMPBELL AVENUE  
MENLO PARK, CA 94025**

**REQUESTER'S RECOMMENDED CLASSIFICATION: CLASS II**

**INDICATIONS FOR USE**

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.

**LIMITATIONS**

Prescription Use only: Federal (USA) law restricts this device to sale by or on the order of a physician.

Limitations on device use are included in the Instructions for Use as Contraindications, Warnings, and Precautions

## Contraindications

The Patient must not have known or active medical issues that would preclude having a hearing device, including:

- an abnormal tympanic membrane (TM) (deemed perforated, inflamed or has a dimeric or monomeric area, or in any other way abnormal);
- an abnormal middle ear or a history of prior middle ear surgery other than tympanostomy tubes;
- an ear canal anatomy that prevents the physician from seeing an adequate amount of the tympanic membrane;
- an anatomical configuration of the external auditory canal that prevents satisfactory placement of the Tympanic Membrane Transducer (TMT);
- a history of chronic and recurrent ear infections in the past 24 months;
- a rapidly progressive or fluctuating hearing impairment;
- diagnosed with having a compromised immune system which may impact the tissue of the auricle or ear canal, such as keratosis obturans, ichthyosis, eczema of the auricle or ear canal, or received radiation of the head ever or chemotherapy for cancer within the last six years.

## Warnings

Before using the EarLens™ CHD, read and make sure you understand each of the following safety warnings:

- The EarLens™ Contact Hearing Device is considered MR unsafe. The CHD should be removed prior to an MRI exam or MRI exposure.
- Do not use therapeutic or medical diathermy using electromagnetic radiation (magnetic induction coils or microwave) from the shoulders up with the EarLens™ CHD in place.
- The Behind-the-Ear (BTE) Unit and Ear Tip contain a Class 1 laser product. It is safe to use under normal operating conditions. The Class I laser light is NOT visible. DO NOT look directly into the Laser or aim it directly into your eye. Should the device become damaged, stop using the device and contact your hearing professional.
- If you experience discomfort or pain in your ear, contact your ENT physician immediately.
- Do not insert foreign objects into the ear, such as Q-tips, bobby pins or fingernails. Insertion of foreign objects could result in pain and damage to the ear, damage to the TMT or cause it to operate improperly.
- Contact your hearing professional if you experience discharge from the ear or persistent discomfort or any other problems.
- Should the BTE become unusually warm or hot, promptly remove the BTE and discontinue use. Contact your hearing healthcare professional.

## Precautions

- Individuals with known nickel sensitivity/allergy should be informed that the TMT component contains nickel that is coated with a parylene barrier. If an allergic reaction develops, the TMT should be promptly removed.
- The EarLens™ CHD is a patient-matched design and intended to be used for a single patient.
- You may shower, bathe or swim with the TMT in place. Ear plugs may be used to prevent water from entering the ears so long as care is taken to not over-insert them. Removing water from your ears may be more difficult with the TMT in place.
- Avoid getting the BTE unit wet, as this may damage the device. Remove the BTE unit prior to showering, swimming, or bathing.
- You may experience a reduction in your hearing levels when the TMT is in place but the BTE is not activated.
- Do not direct streams of liquid (i.e. isopropyl alcohol, hydrogen peroxide, DeBrox) into your ears, as this may cause the TMT to become dislodged or cause damage to the devices.
- Failure to oil the ear canal weekly may result in TMT displacement.
- If the EarLens™ BTE fails to operate or if it appears damaged, including the presence of battery leakage or swelling, promptly remove the BTE and discontinue use. Contact your hearing professional.
- Electromagnetic fields produced by other electrical equipment such as cell phones, metal detectors microwaves, RFID systems and commercial theft detection systems (also known as electronic article surveillance [EAS]) may interfere with the CHD. In the event that the patient perceives unexpected noise or interference in the presence of these devices, move away from the source to mitigate the potential interference. Remove the BTE and if you have further concerns, contact your hearing healthcare professional.

PLEASE REFER TO THE LABELING FOR A MORE COMPLETE LIST OF WARNINGS, PRECAUTIONS AND CONTRAINDICATIONS.

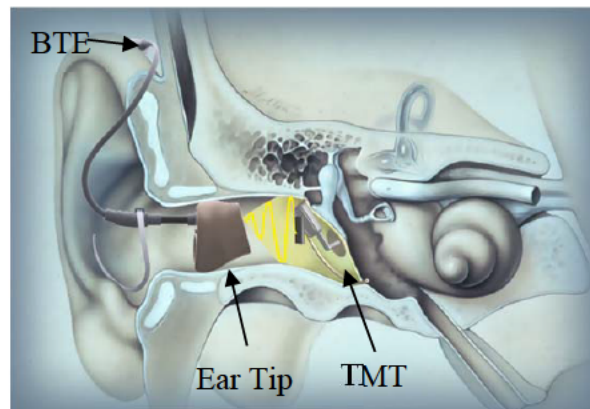
## **DEVICE DESCRIPTION**

The EarLens™ Contact Hearing Device (CHD) transmits amplified sound to compensate for hearing impairment by direct vibration of the tympanic membrane (eardrum). The EarLens™ CHD is composed of an external Audio Processor, which includes a Behind-the-Ear (BTE) Unit and an Ear Tip, a Tympanic Membrane Transducer (TMT), the EarLens™ Fitting Software (ELF), and a Charger with a Power Adapter (Figure 1). In this device, light is used to wirelessly transmit both signal and power from the Audio Processor to the TMT. The BTE sits behind the outer ear, housing the rechargeable battery, digital signal processor (DSP), microphones and drive electronics. The Ear Tip contains the light emitter and directs the light signal down the ear canal.

The TMT resides at the end of the ear canal on the skin around the tympanic membrane. The TMT receives the light signal and converts it into direct vibration of the umbo of the tympanic

membrane. The EarLens™ Charger charges two BTEs at the same time when connected to either the wall power adapter or from the internal battery contained in the Charger. The CHD is patient-matched for single patient use. The ELF enables the hearing professional to program the device specific to the patient's hearing needs. The EarLens™ Impression System is provided to the physician to enable the collection of a deep ear canal impression to create patient-matched TMTs for each patient.

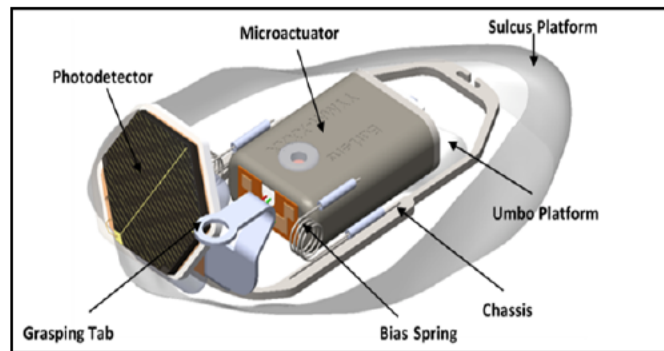
Figure 1: The EarLens™ Contact Hearing Device



### Tympanic Membrane Transducer

The Tympanic Membrane Transducer (TMT) is designed to receive light signals from the Ear Tip and convert the light signals into mechanical vibrations of the tympanic membrane (Figure 2). The TMT is matched for each patient and is placed into position by a physician using the Grasping Tab. It is positioned in the ear at the end of the ear canal on the skin around the tympanic membrane. The Bias Springs, the patient-matched Sulcus Platform, and the Chassis stabilize the TMT in the ear canal, enabling the Umbo Platform to remain in contact with the umbo area of the tympanic membrane. The Photodetector captures the light signals and converts the light energy into current, which activates the Microactuator. The Microactuator vibrates the Umbo Platform, which vibrates the umbo of the tympanic membrane, causing sound to be perceived.

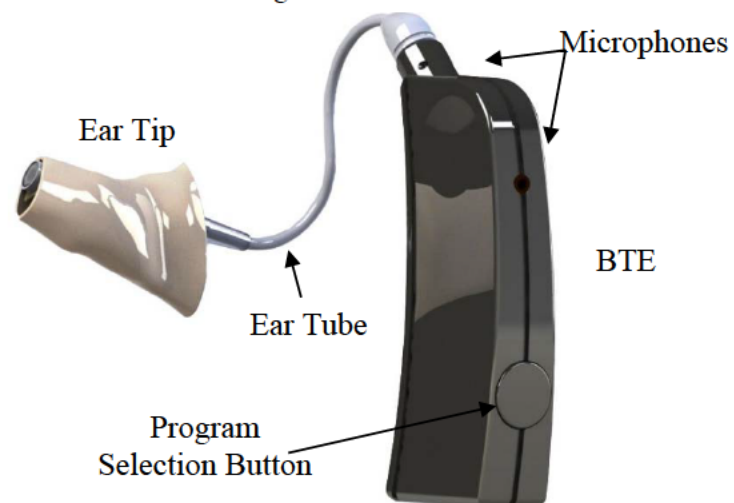
Figure 2: Tympanic Membrane Transducer



### The Audio Processor

The Audio Processor consists of the Behind-the-Ear Unit (BTE) and the Ear Tip. The BTE is directly connected to the Ear Tip via the Ear Tube (Figure 3). The BTE is designed to pick up sounds via the microphone, apply signal processing, and transmit the electrical signal via the Ear Tube to the Ear Tip. The BTE can be removed, replaced, and recharged by the patient. The BTE Case contains two microphones, a digital signal processor, light drive electronics, a Program Selection Button, and a rechargeable battery. The battery is recharged by connecting the Charging Ports to the EarLens™ Charger. The Programming Port enables a hearing professional to program the BTE. The Ear Tube connects the BTE case to the Ear Tip and can be adjusted by a hearing professional. The Ear Tip receives an electrical signal from the BTE and converts this to a light signal using a light emitter. The Ear Tip is a shell with a large opening or vent. The Ear Tip also stabilizes and aims the light emitter at the Photodetector of the TMT.

Figure 3: The Audio Processor



### The EarLens™ Charger

The EarLens™ Charger is designed to recharge the BTEs and act as a storage and travel case. The Charger incorporates Case Wings, BTE Charging Slots, Charging Status LEDs and an AC Adapter Port. When connected to the wall power adapter, the Charger houses and charges either a single BTE or two BTEs simultaneously. If desired, the Charger can be unplugged from the wall and used as a travel case. The Charger incorporates an internal battery, which will charge the BTEs when the Charger is unplugged. An AC wall power adapter is included.

## EarLens™ Fitting Software (ELF)

The EarLens™ Fitting Software (ELF) is used to program the BTE. The ELF enables the hearing professional to calibrate and program the device specific to the patient's needs with up to four programs. In addition to the ELF software, the following devices are required (Figure 4):

- Personal Computer
- HiPro 2 Box with PC communication cable
- Left/Right programming cables for connecting the hearing devices to the HiPro 2

Figure 4: EarLens™ Fitting Accessories



## EarLens™ Impression System

The EarLens™ Impression System is used by the physician to collect a deep ear canal impression. The impression is used to manufacture the patient-matched components of the EarLens™ CHD. Mineral oil (White Mineral Oil, Food Grade) is used to provide the surface tension forces to keep the TMT in position.

The EarLens™ Impression System includes:

- Reusable dispenser
- Lubricating mineral oil (single patient use)
- EarLens™ Impression Material 50 mL dual cartridge (contains enough material for approximately three impressions)
- Mixing tip with stainless steel extension (single use)
- Impression Container (single use)

The EarLens™ Impression System is regulated under 21 CFR Part 874.3300, product code LDG, which is Class I exempt. However, given the risks associated with the deep ear impression procedure, this procedure was assessed to ensure that it can generate reasonably safe and accurate ear impressions that resulted in appropriately fitted EarLens™ CHD device components (TMT and Ear Tip).

## **SUMMARY OF NONCLINICAL/BENCH STUDIES**

Non-clinical/bench studies conducted on the EarLens™ CHD to demonstrate a reasonable assurance of safety and effectiveness of the device are summarized in the sections below.

### **BIOCOMPATIBILITY / MATERIALS**

The EarLens™ CHD contacts the patient's intact skin surfaces and is therefore characterized as a skin surface contacting device. The TMT is categorized as a permanent contact device as the device is intended to be used more than 30 days. The Audio Processor and Charger are categorized as temporary contact devices intended to be used less than 24 hours at a time. In accordance with ISO 10993-1: Biological Evaluation of

Medical Devices, Part 1: Evaluation and Testing within a Risk Management Process, the following biocompatibility testing was conducted on the EarLens™ CHD. The biocompatibility assessment was deemed adequate.

Table 1: Summary of Biocompatibility Test Results for EarLens™ CHD

<b>Component Tested</b>	<b>Test Requirement</b>	<b>Test Results</b>
EarLens™ CHD System (TMT, BTE, Ear Tip) and Charger	<i>MEM elution Cytotoxicity per ISO 10993-5</i>	<i>Pass</i>
EarLens™ Ear Tip (soft)		<i>Pass</i>
EarLens™ System (TMT, BTE, Ear Tip)	Tests skin sensitization <i>per ISO 10993-10</i>	<i>Pass</i>
EarLens™ System (TMT, BTE, Ear Tip)	Tests for irritation <i>per ISO 10993-10</i>	<i>Pass</i>

Furthermore, the EarLens™ TMT was tested for Nickel leaching per the requirements of EN1811, which is a European standard and the levels of Nickel were found to be within the safe levels per the standard. Although no nickel leaching was noted, results of the 14 day soak test in simulated sweat solution suggest that traces of oxidation (discoloration) may be visible on the TMT surface following prolonged wear. Performance testing indicated that this is not likely to affect the structural integrity of the TMT within the 1 year expected device life. Because the oxidation (discoloration) was contained beneath the parylene coating, this should not pose a safety risk.

#### **SHELF LIFE/STERILITY**

The EarLens™ CHD is provided non-sterile. The expected service life of the EarLens™ CHD and all accompanying components of the system is one year, based on the results of the mechanical and reliability testing. The BTE and Ear Tip can be cleaned with a soft cloth. Liquid cleaners should not be used on the BTE as these can damage the device.

#### **ELECTROMAGNETIC COMPATIBILITY TESTING**

The requester conducted electromagnetic compatibility testing on the EarLens™ CHD and its respective components and subcomponents, as applicable, to provide a reasonable assurance of safety of the device.

During all the electromagnetic compatibility (EMC) tests, the BTE and light emitting Ear Tip were coupled to a TMT placed in a mold representative of the anatomical shape of the ear. The Ear Tip was placed at a fixed distance from the TMT and optically coupled to it. The BTE was programmed to output a 1000 Hz acoustic tone at a level 3dB below the full scale. The digital representation of the 1000 Hz tone was encoded into light pulses by the laser housed in the Ear Tip and emitted onto the TMT. The audio signal received at the TMT was monitored. During the EMC tests, continuous monitoring of this signal ensured that the laser output remained stable in the presence of external EM fields generated during the testing and that these external EM fields did not induce any energy in the TMT. The acceptance criteria

for the variation of this signal was selected to be less than 3dB because this represents a typical volume adjustment step size in audio instruments, including common hearing aids. No variation of more than 3dB was observed during the EMC testing, demonstrating adequate EMC performance of the device system.

### Emissions and Immunity Testing

EMC for the EarLens™ CHD was tested for both the normal use of the device and the charging operation. The testing was done in accordance with the FDA recognized standard, IEC 60601-1-2 Ed. 3.0, 2007-03-30, Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral standard: Electromagnetic Compatibility - Requirements and Tests. This testing also was conducted at higher compliance limits per the FDA guidance document, *Design Considerations for Devices Intended for Home Use*, (issued on November 24, 2014), to demonstrate immunity to the following levels for the home environment:

- Electrostatic Discharge (ESD): +/- 8kV contact discharge and +/- 15kV air discharge
- Power frequency magnetic fields: 30 A/m at 50 Hz or 60 Hz
- Conducted RF: 3 V r.m.s outside of ISM and amateur radio bands between 0.15 MHz and 80 MHz; 6 V r.m.s in ISM and amateur radio bands between 0.15 MHz and 80 MHz
- Radiated immunity (RF EM fields): 10 V/m 80 MHz - 2.6 GHz

All tests passed at the higher test levels stated above, which supports immunity at these levels and use of the device in the home environment. Furthermore, in order to assess immunity of EarLens™ CHD on board an aircraft, testing was conducted per the requirements of RTCA DO-160 Section 20 (RF Immunity) Category T, Radio Technical Commission for Aeronautics: Radio Frequency Susceptibility – Well Protected Location, with passing results.

### Immunity Tests with Intentional Radiators

In addition, the performance of the EarLens™ CHD was tested in close proximity with intentional radiators, such as cell phones and metal detectors (Table 2). The EarLens™ CHD was placed within 5 cm of each intentional radiator individually to simulate user interaction with the equipment. The EarLens™ CHD was rotated to expose all six sides of the device to the intentional radiator. The BTE was programmed to transmit a 1 kHz tone and the level of tone was continuously monitored at the TMT in presence of the intentional radiators. Acceptance level was set such that the audio level at the TMT remained within +/-3dB of the original level when the intentional radiator was not present.

The following equipment was tested with passing results supporting immunity:

- Cell phones (800MHz/1900MHz)
- Wireless 2.4GHz router
- Cordless phones (900MHz/2.4GHz)
- CB radio 27MHz
- Family Radio 460MHz



- Microwave oven
- Portable radio 150MHz
- Land line phone receiver
- RFID readers
- Metal detectors (pulse induction)
- Electronic article surveillance (EAS) system

Table 2: Description of Intentional Radiators Used for Testing

Item #	Equipment Description	Manufacturer	Model	Serial number	RF Output Power	Operating Frequency
1	Wireless Broadband Router - Access point	b(4)	(4)		0.083 Watts	2.4 GHz
2	Portable 2-Way Radio				2 Watts	150 MHz – 170 MHz
3	Family Radio Service Band Walkie Talkie				0.46 Watts	460 MHz
4	Cordless Phone				88 dBuV/m @ 3m	2.4 GHz
5	Citizen Band CB Radio				4 Watts	27 MHz
6	Cordless Phone				88 dBuV/m @ 3m	900 MHz
7	Cell Phone				1.8 Watts (800MHz) 1.4 Watts (1900MHz)	800 MHz, 1900 MHz
8	Cell Phone				0.7 Watts (800MHz) 1.6 Watts (1900MHz)	800 MHz, 1900 MHz
9	Microwave Oven				800 Watts	2.4 GHz
10	RFID Tag/ Reader				N/A	125 kHz
11	Land Line Phone Receiver				N/A	N/A
12	Metal Detector				N/A	7 kHz
13	EAS System				N/A	58 kHz
14	EAS System				N/A	58 kHz
15	EAS System				N/A	58 kHz
16	EAS System				N/A	58 kHz

During the immunity testing, no degradation of performance was observed, indicating that the EarLens™ CHD has high immunity against a range of potential interferers that may be encountered in daily use. Higher intensity or different configurations of potential interferers may negatively impact coexistence in ways not observed here. As an added warning, the device labeling (including patient manual) includes the recommendation from IEC60601-1-2:2007 on the minimal distance to avoid different interferers of different frequencies and output levels.

## SOFTWARE

### Level of Concern

The requester identified the Level of Concern for the EarLens™ CHD as Minor based on their answers to the questions listed in Table 1 (Major Level of Concern) and Table 2 (Moderate Level of Concern) of the FDA guidance document, *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*. Consequently, the requester states that any failure or design flaws in the software are unlikely to cause any injury to the patient or to the (clinician) operator. Given that the device maximum equivalent pressure output (MEPO, discussed below) is appropriately limited based on the device design and the selection and tolerance of the various device hardware components including the BTE (e.g., battery, DSP, and laser diode) and TMT (photodetector and microactuator), this assessment for software risk is reasonable.

### Software Description

EarLens™ software is designed in accordance with the guidance of ISO 13485 and ISO 62304, Medical devices -- Quality management systems -- Requirements for regulatory purposes and ISO 62304, Medical device software -- Software life cycle processes, and is very similar to software used in fitting air conduction hearing aids. The fitting software controls the parametric settings of the hearing aid and DSP firmware applies these values in the fitting of the EarLens™ CHD. During the fitting process, clinicians specify the parametric values of the device programs by entering values from their keyboards of the PC. The DSP firmware applies these values by writing these values into the hardware.

The EarLens™ Fitting Software (ELF) is used to program the BTE. The ELF software enables the hearing professional to calibrate and program the device specific to the patient's needs. In addition to the ELF software, the following devices are required:

- Personal Computer, Windows 7 platform (details below)
- HI-PRO 2 Box with PC communication cable
- The HI-PRO 2 box [GN Otometrics A/S] is a standard programming interface for many hearing aid systems. It connects to a computer using a USB interface and to the hearing aid using programming cables. The HI-PRO 2 is powered from the USB interface. The HI-PRO 2 has the following additional characteristics:
  - Safety: EN 60601-1, Type BF
  - Electromagnetic Compatibility: EN 60601-1-2
  - Systems: EN 60601-1-1 or IEC 60601-1, 3<sup>rd</sup> ed.
  - Hearing Instrument Interface: EN 60118-14
- Left/Right programming cables for connecting the EarLens™ BTEs to the HiPro 2 via the programming ports. These cables are available from a number of hearing aid industry supplier b(4) ]. The 4 pin CS44 is compatible with the EarLens™ CHD.

The ELF software is stored on a Compact Disc (CD) and is installed using an industry standard installation package and can be run from an icon on the desktop.

Device Software Hazard Analysis

The potential hazard associated with the use of the device is the potential occurrence of uncomfortably loud sounds. The hearing aid may cause momentary discomfort at the time of the occurrence. This hazard is mitigated by limiting the hearing aid output to below the patient’s loudness discomfort level.

Software Requirement Specification

The fitting software is used to program the parameters and the DSP firmware applies these values in the hardware. b(4)

Standard PC peripherals include a monitor with 1024x768 resolution, mouse and a keyboard. b(4)

Verification and Validation

The software is verified using functional testing against requirements, unit tests and moreover, the clinical study validates that the compression algorithms functions as designed.

Revision Level History

The software is version controlled and the revision history is maintained. The latest version is 1.0.3.0 and version 1.1.20 for the DSP firmware.

**PERFORMANCE TESTING - BENCH**

The requester conducted performance testing on the EarLens™ CHD to support a reasonable assurance of safety and effectiveness of the device. All of the testing described below was conducted on final versions of the TMT, BTE, Ear Tips and Chargers (or final subassemblies) which were manufactured in the final form using representative production processes. Appropriate sample sizes were justified. Table 3 provides a summary of each of the bench test purpose, methods, acceptance criteria, and results. In sum, the bench testing was deemed adequate and supports an expected device life of 1 year.

Table 3: Summary of Bench Testing

Test Standard/Method	Test Purpose/Description	Component(s) Tested	Acceptance Criteria	Results
----------------------	--------------------------	---------------------	---------------------	---------

IEC 60601-1 Standard for medical electrical equipment: General requirements on basic safety and essential performance	To demonstrate that EarLens™ CHD meets general safety requirements	<ul style="list-style-type: none"> <li>• TMT</li> <li>• BTE</li> <li>• Ear Tip</li> <li>• Charger</li> </ul>	Per the standard requirements	All tests Passed and requirements of IEC 60601-1 Edition 3.0, 2005-12 were met.
IEC 60601-1-11 Collateral standard for medical electrical equipment and medical electrical systems used in the home healthcare environment	To demonstrate that EarLens™ CHD is safe to use in the home environment	<ul style="list-style-type: none"> <li>• TMT</li> <li>• BTE</li> <li>• Ear Tip</li> <li>• Charger</li> </ul>	Per the standard requirements	All tests Passed and requirements of ANSI/AAMI (IEC) 60601-1-11:2010 were met.
IEC 60825-1 Standard for safety of laser products: equipment classification and requirements	To demonstrate that the laser used in EarLens™ CHD is safe and classified as Class I laser product	<ul style="list-style-type: none"> <li>• BTE</li> <li>• Ear Tip</li> </ul>	Per the standard requirements	All tests Passed and the output of the laser used was found to be well within the safe accessible emission levels (AEL) and maximum permissible exposure (MPE) levels for eye and skin. EarLens™ CHD was classified as a Class I laser product per the IEC 60825-1.
ASTM D4169 Standard practice for performance testing of shipping containers and systems	To demonstrate EarLens™ CHD can be reliably shipped	<ul style="list-style-type: none"> <li>• TMT</li> <li>• BTE</li> <li>• Ear Tip</li> <li>• Charger</li> </ul>	Per the standard requirements	All tests Passed and requirements of ASTM D4169 were met.
<b>Electrical Testing</b>				
Output Limiter Test Measure worst case battery current and the laser output	To demonstrate the output limiter limits the laser output for safe	<ul style="list-style-type: none"> <li>• BTE</li> <li>• Ear Tip</li> </ul>	Battery current is limited to 12 mA ± 1 mA at battery voltage 4.2V.	Passed

	operation			
<p>Harmonic Distortion Test</p> <p>Measure harmonic distortion at the BTE output with a 1kHz tone at -3dB re FS</p> <p>Measure harmonic distortion at the TMT output with a frequency sweep up to 10,000 Hz at -3dB re FS light input</p>	To demonstrate the distortion of the EarLens™ CHD is low	<ul style="list-style-type: none"> <li>• BTE</li> <li>• Ear Tip</li> <li>• TMT</li> </ul>	Distortion is less than 5%	Passed
<p>Maximum Output Test</p> <p>Measure average maximum equivalent pressure output (MEPO) in human temporal bones</p>	To demonstrate that the maximum output of EarLens™ CHD does not exceed 132dB SPL	<ul style="list-style-type: none"> <li>• BTE</li> <li>• Ear Tip</li> <li>• TMT</li> </ul>	Average maximum equivalent pressure output (MEPO) is ≤132 dB SPL	Passed
<b><i>Mechanical and Reliability Testing</i></b>				
<p>Ear Tip Pull Test</p> <p>Check the Ear Tip cable integrity during and after repeated application of 8oz. of force at the connector end of the cable</p>	To assess reliability of the Ear Tip	<ul style="list-style-type: none"> <li>• Ear Tip</li> </ul>	Ear Tip cable withstands 8 oz. of pull force at the connector for 1095 cycles	Passed
<p>Ear Tip Bend Test</p> <p>Check the Ear Tip cable integrity during and after repeated application of a 150° bend to the cable from its nominal position at</p>	To assess reliability of the Ear Tip	<ul style="list-style-type: none"> <li>• Ear Tip</li> </ul>	Ear Tip cable withstands 150° bend for 1095 cycles	Passed

the point where the cable is expected to enter the ear canal				
<p>Ear Tip Twist Test</p> <p>Check the Ear Tip cable integrity during and after repeated application of a 150° twist to the cable from its nominal position at the connector to the BTE</p>	To assess reliability of the Ear Tip	<ul style="list-style-type: none"> <li>• Ear Tip</li> </ul>	Ear Tip cable withstands 150° twist for 1095 cycles	Passed
<p>Accelerated Aging Test - TMT</p> <p>Test performance of TMT after 1 year of simulated aging at 65°C</p>	To assess reliability of adhesive bonds and components	<ul style="list-style-type: none"> <li>• TMT</li> </ul>	No performance degradation in TMT output and adhesive bond strengths	Passed
<p>Accelerated Aging Test – Ear Tip</p> <p>Test performance of Ear Tip after 1 year of simulated aging at 75°C</p>	To assess reliability of adhesive bonds and components	<ul style="list-style-type: none"> <li>• Ear Tip</li> </ul>	<p>Less than 10% degradation in laser output</p> <p>No degradation in adhesive bond strength when Ear Tip cable is repeatedly subjected to 10N force at the connector end for 26 cycles</p>	Passed

<p>Maximum force on the Umbo of the eardrum</p> <p>Measure bias force exerted by the Umbo Platform of the TMT under worst case orientation of the device where effects of gravity are additive</p>	<p>To ensure safe operation of TMT</p>	<ul style="list-style-type: none"> <li>• TMT</li> </ul>	<p>Maximum force exerted on the Umbo of the eardrum by the TMT is <math>\leq 6\text{mN}</math></p>	<p>Passed</p>
<p>Mechanical strength – grasping tab</p> <p>Apply and measure force using a force gauge coupled to the grasping tab while the chassis is held in fixed position and increase force until component failure is observed</p>	<p>To ensure grasping tab remains intact with forces arising from manipulation by the physician</p>	<ul style="list-style-type: none"> <li>• TMT</li> </ul>	<p>Grasping tab will withstand pull forces of at least 1N</p>	<p>Passed</p>
<p>Mechanical strength – Umbo Platform</p> <p>Apply and measure force using a force gauge coupled to the drive-post, while the Umbo Platform is held in fixed position and increase force until component failure is observed</p>	<p>To ensure the umbo platform does not separate</p>	<ul style="list-style-type: none"> <li>• TMT</li> </ul>	<p>Umbo Platform will withstand forces of at least 0.25N</p>	<p>Passed</p>

### IEC 60601-1 Testing

The EarLens™ CHD was tested per the requirements of IEC 60601-1, Edition 3.0, 2005-12, Standard for medical electrical equipment: General requirements on basic safety and essential performance to provide reasonable assurance of the basic safety and essential performance of the device. These tests included power consumption test, humidity preconditioning, determination of applied parts and accessible parts, durability and legibility of markings test, leakage current test, patient leakage test, dielectric strength test, ball pressure test, creepage distances and air clearances, sharp edges test, instability in transport position test, instability excluding transport test, normal heating test, ingress of liquids,

hazardous situations and fault conditions test, rigidity of enclosure (push) test, strength of enclosure (impact) test, drop impact, and mold stress relief test. All tests passed.

#### IEC60601-1-11 Testing

The EarLens™ CHD is expected to be used predominately by an older population (>60 years of age) based on the ages of the study subjects in the clinical studies. It was therefore determined that compliance with IEC 60601-1-11:2010 is necessary. This standard applies to the basic safety and essential performance of medical electrical equipment and medical electrical systems which are intended by the manufacturer for use in the home healthcare environment, regardless of whether the medical electrical equipment or medical electrical system is intended for use by a lay operator or by trained healthcare personnel. The object of IEC 60601-1-11:2010 is to specify general requirements that are in addition to those of the general standard IEC 60601-1:2005 and to serve as the basis for particular standards. Compliance testing to this standard was successfully completed and EarLens™ CHD demonstrated basic safety and essential performance as it pertains to medical equipment in the home healthcare environment following the guidelines of the ANSI/AAMI HA606061-1-11:2010 version of this home healthcare environment standard.

These tests include environmental conditions of transport and storage between uses, environmental operating conditions, shock test for mechanical strength for transit-operable ME equipment, and broad-band random vibration test for mechanical strength for transit-operable ME equipment.

#### IEC60825-1 Testing

The EarLens™ CHD was tested per the requirements of IEC 60825-1, Safety of Laser Products, and was classified as a Class I laser product. The output of the laser used in the EarLens™ CHD was found to be well within the safe accessible emission levels (AEL) and maximum permissible exposure (MPE) levels for eye and skin.

These tests include measurement of laser radiation and measurement of pulse width and demonstrate safe operation of the laser used in the EarLens™ CHD. Additionally, as part of the clinical study described below, a 'roll-in cohort' of 10 ears (5 subjects) underwent multiple temperature measurements within their ear canal after at least 8 hours of continuous use with the CHD and exposure to the laser. The results showed that there was less than 1°C temperature rise in the ear canal, further demonstrating the safe operation of the laser used in the EarLens™ CHD.

#### Electrical Testing

Extensive testing was conducted on the EarLens™ CHD to verify the design criteria and device performance with respect to the electrical system specifications and properties in support of its safety and effectiveness. The BTE Audio Processors, Ear Tips and Chargers were tested in finished form and passed the following tests: total harmonic distortion, maximum output, output noise, microphone directionality, programmable settings, dielectric



strength and leakage current, battery charge time, light output, electromagnetic emissions and immunity. The TMTs were tested in finished form and passed the following tests: total harmonic distortion and vibrational response at -3dB re F.S. and -20dB re F.S. input levels, electromagnetic emissions and immunity.

### Mechanical and Reliability Testing

Extensive testing was conducted on the EarLens™ CHD to verify the design criteria and device performance with respect to the mechanical system specifications and properties in support of reasonable assurance of safety and effectiveness.

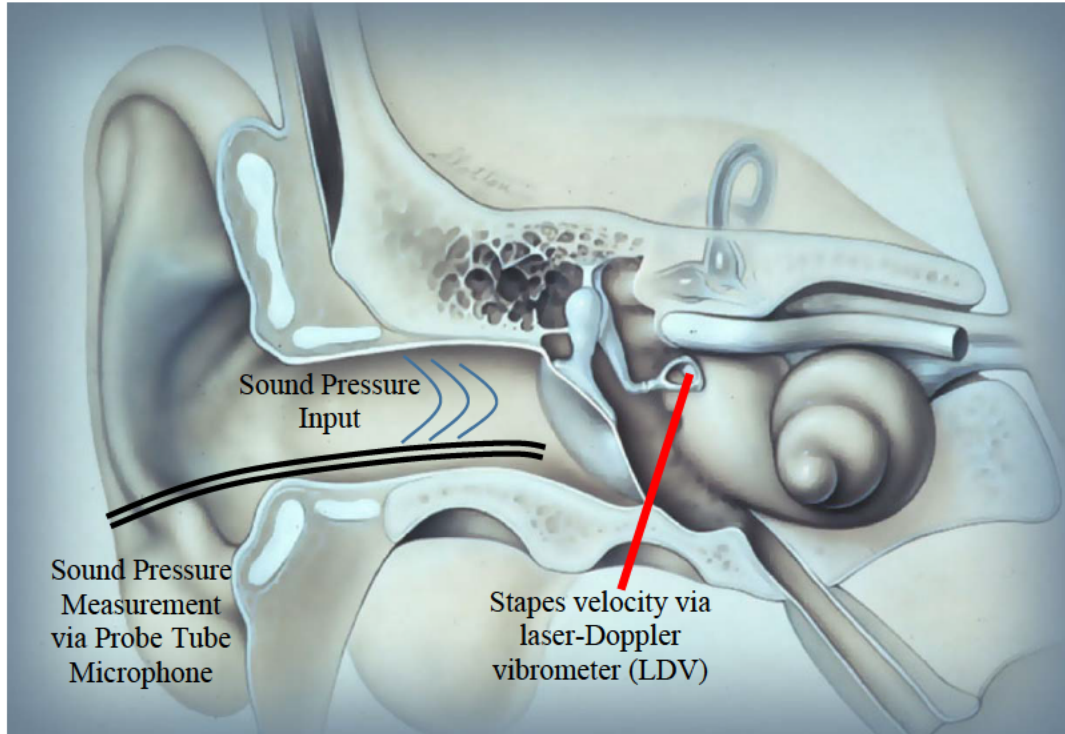
The BTE Audio Processors, Ear Tips and Chargers were tested in finished form and passed the following tests: operating conditions, storage conditions, Ear Tip pull test, Ear Tip bend test, Ear Tip twist test, accelerated aging test, liquid/dust ingress test, BTE mechanical strength test, BTE dimensional measurements, Ear Tip vent hole dimensional check, BTE connector torque test, and shipping and environmental tests per ASTM D4169-09.

The TMTs were tested in finished form and passed the following tests: TMT dimensional check, TMT mass, TMT bias force test, TMT adhesive bond strength tests, tensile tests, accelerated aging and fatigue test, shipping and environmental tests per ASTM D4169-09. The maximum worst-case force applied to the umbo under normal conditions was measured and determined to be at a safe limit. The information provided is adequate validation of the force applied to the tympanic membrane (< 6mN) using an appropriate model. Accelerated fatigue testing included a finite element analysis of the microactuator reed and a cyclic fatigue analysis of the bias springs to show that the device is likely to maintain its structural integrity and function for at least 1 year of use under worst case conditions. Tensile testing was performed after accelerated aging in order to confirm long term adhesive bond strength.

### Temporal Bone Testing

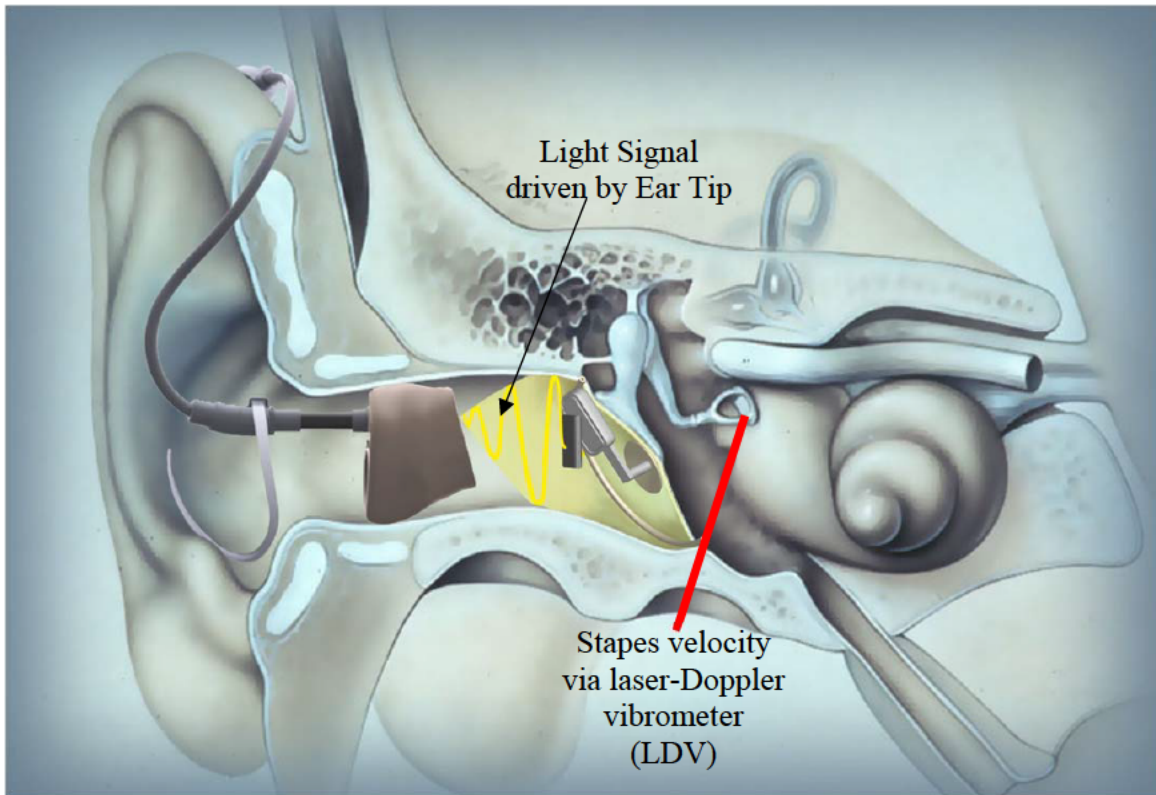
As part of the non-clinical validation, a temporal bone model was used to ensure that the output of the system was within the expected range. In this validation, a calibrated Laser-Doppler Vibrometer (LDV) was used to measure the amplitude of motion of the footplate of the stapes on four temporal bone samples. In each case, the tympanic membrane was exposed to acoustic energy at frequencies between 100Hz and 24,000Hz, and a probe microphone was used to measure the sound pressure level at the tympanic membrane. The sound pressure level and stapes motion were measured simultaneously, and a transfer function determined for each frequency measured (Figure 5a).

Figure 5a: Stapes Velocity Measurements with an acoustic input



Next, for each temporal bone sample, a CHD system was placed and activated in a normal fashion (see Figure 5b). The stapes motion and CHD output signal were recorded and a second transfer function recorded. The two measurements can be correlated to determine the output at full scale, or Maximum Equivalent Pressure Output (MEPO).

Figure 5b: Stapes velocity measurement with a vibratory input



In order to determine the equivalent output of the system in a worst case condition, the emitter was positioned so that all of the light energy was focused on the photodetector of the TMT and the MEPO again determined. In addition to the MEPO calculation based on moderate sound pressure levels, the CHD was driven to full scale output for both the nominal and worst case emitter positions. The testing demonstrated that the overall mean maximum equivalent pressure output (MEPO) of the system on four temporal bone samples was 127dB SPL. This is an acceptable maximum equivalent pressure output for the device. The information provided is adequate validation of the output applied to the tympanic membrane in a clinically appropriate model.

#### Magnetic Resonance Imaging (MRI) Safety

The TMT contains an electromagnetic actuator and ferromagnetic materials that could lead to patient injury or device damage during exposure to a magnetic resonance environment. To mitigate this risk, the device is labeled “MR Unsafe.” In addition, a patient card is required to be provided to the patient, which instructs physicians to remove the TMT from the eardrum prior to performing an MRI examination.

#### SUMMARY OF CLINICAL INFORMATION

The following is a summary of two clinical studies performed by the sponsor to support a reasonable assurance of safety and effectiveness for the EarLens™ CHD.

### Ear Impression Study

EarLens™ conducted an impression study to collect ear impressions from many different ear canal anatomies, which provided validation of the deep canal impression procedure itself. This ear impression procedure involves making a mold deep into the canal and including the tympanic membrane and thus, is considered to involve slightly more risk than typical ear impression procedures for conventional types of hearing aids. The procedure will be performed by a healthcare professional trained in this particular ear impression procedure.

A total of 78 subjects had bilateral ear canal impressions taken (37 female, 41 male). The total number of ears that had impressions taken was 154 (2 subjects had unilateral impressions). Subject age ranged from 32 to 82 years with an average of 66.1 years. The subjects were seen across three clinical sites.

A total of 200 ear impressions were taken on 154 ears (78 subjects). Fourteen subjects (18%) required more than one clinic visit to obtain adequate ear impressions. Multiple impressions were required on some subject ears due to the presence of voids in the impression of anatomical areas that are critical to the patient-matched transducer. The average number of impressions per subject was 2.6, or 1.3 per ear. Thirty-eight percent (38%) of subjects required three or more impressions; 17% required four or more impressions.

Based on a subject survey, a total of 84% of impressions were rated as either no discomfort or mild discomfort. While 80% of the study ears were observed to be normal (unremarkable otoscopic inspection) after the impression procedure, the remaining ears were reported with minor skin contact findings. The most common observation was a micro-hematoma (16%), while petechia (1%), ecchymosis (2%) and abrasion (1%) were reported less frequently. All otologic findings resolved without treatment and without sequelae. Micro-hematomae and ecchymoses can take 2-4 weeks to resolve. Abrasion and petechia, depending on extent and location, can be a more minor finding and may or may not require delay of subsequent otologic procedures, including transducer placement.

Given the nature of this ear impression procedure, the numbers of adverse events reported above are anticipated and acceptable. No major or permanent trauma to the ear canal or tympanic membrane was noted. In order to minimize adverse events, training in this type of ear impression procedure will be necessary and designated as a special control to fit the EarLens™ CHD.

### Pivotal Clinical Study

A clinical study of the EarLens™ CHD confirmed a reasonable assurance of safety and effectiveness of the device for individuals with a mild to severe sensorineural hearing impairment between the frequencies of 125 Hz to 10,000 Hz. This prospective, single arm, open label study assessed 48 subjects (96 ears) who wore the fully activated system in both ears in their daily lives for four months per study protocol. The subjects served as their own controls, with outcomes

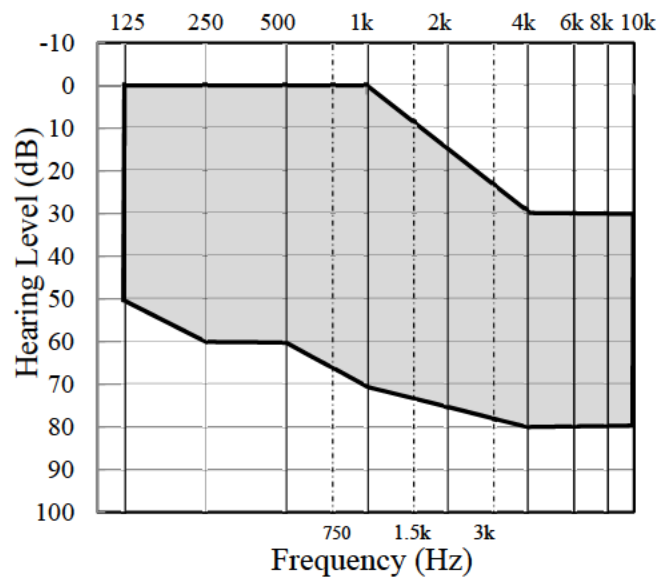
comparing the unaided (no treatment) condition to the aided (treatment with the EarLens™ CHD) condition. Safety and effectiveness were assessed during the four months.

The average age of the study population was 69 years with gender ratio at 60% for males and 40% for females. The subjects were seen across three clinical sites with the largest enrollment at Site 1 (Site 1= 21, Site 2=15, Site 3=12). All subjects were experienced hearing aid users who met the inclusion and exclusion criteria.

The inclusion criteria were:

1. Age 18 to 85 years;
2. Mild to severe hearing impairment within the fitting range shown below: One frequency may fall outside range for each ear;

Freq (Hz)	125	250	500	1000	2000	4000	6000	8000	10000
HL min (dB)	0	0	0	0	15	30	30	30	30
HL max (dB)	50	60	60	70	75	80	80	80	80



3. Symmetric hearing impairment; no more than a 15 dB difference in thresholds between the ears at five of eight tested frequencies (125, 500, 1000, 2000, 4000, 6000, 8000, and 10,000 Hz).
4. The difference between the diagnostic word recognition scores (Northwestern Auditory Test No. 6 (NU-6)) between the two ears for a given subject must not exceed 25% to reduce the possibility that a subject may have retrocochlear involvement.
5. No significant conductive hearing impairment;
  - a. No more than a 10 dB air-bone gap at three of four tested frequencies (500, 1000, 2000, or 4000 Hz);
  - b. Normal Type A tympanometry (indicating normal mobility of the tympanic membrane (TM) and middle ear ossicles).

6. Greater than or equal to 60% on maximum word recognition score using a 50-word NU-6 list for each ear measured at a presentation level determined by the threshold at 2000 Hz and presented over inserts or earphones demonstrating an ability to benefit from amplification.
7. Current unilateral or bilateral user of hearing aids for at least 6 weeks prior to study enrollment.
8. Able and willing to commit to the travel and time demands of the study (available for six months or longer) and able to comprehend and comply with the study materials and instructions.
9. Native speaker of American English due to use of American English study materials.

The exclusion criteria were:

1. Must not have known or active medical issues that would preclude having the study device, including:
  - a. abnormal TM (deemed perforated, inflamed, sclerotic, or has a dimeric or monomeric area, or in any other way abnormal);
  - b. Abnormal middle ear or a history of prior middle ear surgery other than tympanostomy tubes;
  - c. Ear canal anatomy that prevents the physician from seeing an adequate amount of the TM, or an anatomical configuration of the external auditory canal that prevents satisfactory placement of the TMT (examples include a large anterior canal bulge and exostoses of the ear canal).
2. Must not have other known or active medical issues including:
  - a. History of chronic and recurrent ear infections in the past 24 months;
  - b. History of dizziness and/or vertigo in the past 24 months;
  - c. Currently taking medications/treatments with known ototoxic effects;
  - d. Rapidly progressive or fluctuating hearing impairment;
  - e. Diagnosis of a compromised immune system which may impact the tissue of the auricle or ear canal, keratosis obturans, ichthyosis, eczema of the auricle or ear canal, or received radiation of the head ever or chemotherapy for cancer within the last six months.
3. Must not fit the definition of a vulnerable subject, as per FDA regulations 21 CFR Parts 50 and 56.
4. Must not have an ear canal anatomy that precludes manufacture of the TMT as determined by EarLens™ manufacturing personnel. The manufacturing personnel will be independent from the personnel evaluating the audiological data.

## Safety Results

The primary safety endpoint was intended to demonstrate that use of the EarLens™ CHD did not result in a change in residual hearing function. The objective was to identify any change in baseline hearing after four months of device usage using a four frequency threshold criteria (500, 1000, 2000, and 4000 Hz, referred to as PTA4). A determination of clinically non-significant hearing threshold change was made if the calculated PTA4 hearing change of the subject population was less than 10 dB. After wearing the TMT for 4 months, no decrease in hearing

sensitivity of more than 10 dB was observed. A secondary safety endpoint assessed any decrease in hearing sensitivity of >10 dB by subject per ear at each test frequency. After four months of use, no subjects exhibited a decrease of >10 dB at either ear by frequency. In addition, no serious device or procedure-related adverse events (AEs) were reported during the trial. There were 31 AEs reported in 20 subjects at 22 ears. All but one of the AEs was temporary and resolved. One subject reported a ‘fullness’ sensation when wearing the CHD, which did not change during the trial but effectiveness outcomes for this subject were not impacted. The subject continued use throughout the study period of four months. The event is unresolved because the subject elected to participate in the protocol extension and had the devices replaced after the 4-month study period. The following table (Table 4) identifies the AEs by type, frequency of occurrence and resolution status at the active study end.

Table 4: Adverse events across study period

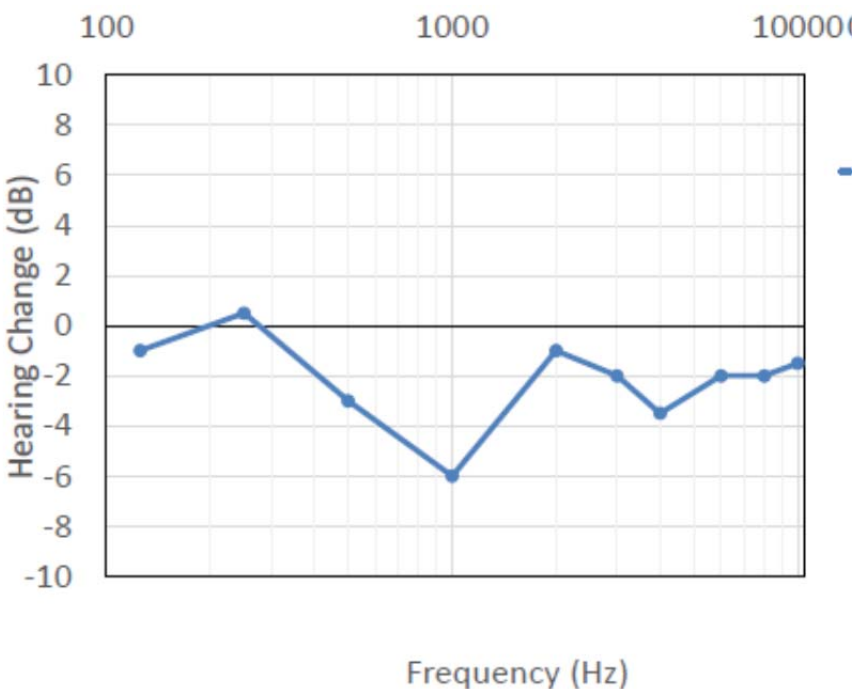
<b>Adverse Event Category</b>	<b>Number Occurring</b>	<b>Serious AE</b>	<b>Status</b>
Abrasion/blood blister in ear canal	17	No	Resolved
Ear discomfort/pain	5	No	Resolved
Inflammation/granulation tissue on tympanic membrane	3	No	Resolved
Abrasion/blood blister on tympanic membrane	2	No	Resolved
Ear tip-related: Ear canal swelling, itching, etc	2	No	Resolved
Pain upon eructation & valsalva	1	No	Resolved
Sensation of fullness	1	No	Ongoing

In addition, images of the subjects’ tympanic membranes were taken pre- and post-4 months of EarLens™ CHD wear. These images (n=78 ears) were reviewed and were unremarkable. No significant safety concerns were noted.

In order to assess the risk of overheating of the ear canal from the light source transducer (laser diode), 5 roll-in subjects were enrolled in a pilot phase of the study for this safety analysis. Ear canal temperature measures in the 5 roll-in subjects (10 ears) showed no rise in ear canal temperatures after 8 continuous hours of device use. This clinical validation, in conjunction with the non-clinical testing of the laser diode, provides a reasonable assurance of the safety of this component of the EarLens™ CHD.

Hearing thresholds were measured with the TMTs in place, but without the audio processor, in order to assess the potential temporary tympanic membrane damping that may occur as a result of having a device in continuous contact with the surface of the tympanic membrane. The TMTs are designed to remain in place even when the Audio Processor is not worn. When the audio processor is removed (swimming, bathing, sleeping), users may experience tympanic membrane damping, which would be interpreted as slight reduction of sound beyond that already caused by their hearing loss, due to the loading effect of the TMT. The amount of damping observed varied, but the effect on PTA (500Hz, 1000 Hz, and 2000 Hz) averaged 4 dB of damping, which is immediately reversed when the TMT is removed. The maximum amount of damping observed was 20 dB at a single frequency. The amount of damping stayed essentially the same for the duration of the 4 month study. When the audio processor is in place, the gain delivered by the EarLens™ CHD more than overcomes the TM damping effect. Figure 6 shows the average amount of damping observed across the frequency range 125-10000 Hz (n=90 ears).

Figure 6: Damping of hearing from presence of TMT compared to unaided baseline



Effectiveness Results

The primary efficacy endpoint was intended to demonstrate device effectiveness by improving speech recognition using the Northwestern Auditory Test No.6 (NU-6) of word recognition with the EarLens™ CHD at a speech level of 45 dB HL. The objective was to show that the EarLens™ CHD provides a statistically significant improvement in mean aided word recognition at 30 days post placement when compared to the baseline unaided condition measured prior to placement. The average baseline unaided score was 52% and the average aided score was 85% (see Figure 7); this improvement was statistically significant (p<0.0001) and very clinically



meaningful with an average of 33% improvement in word recognition ability at a soft listening level.

A secondary measure of device effectiveness was defined as more than 10 dB improvement (functional gain) in thresholds over the range of frequencies from 2000 to 10000 Hz for the aided condition measured at 30 days post placement when compared to unaided condition measured prior to placement of the EarLens™ CHD. Mean functional gain was 30.5 dB ( $p < 0.0001$ ), indicating that the EarLens™ CHD was able to deliver significant functional gain (see Figure 8). Functional gain reached a maximum of 68 dB at 9-10k Hz, which is not typically achieved with conventional air-conduction hearing aids.

These primary and secondary measures of device effectiveness were repeated at later time intervals in order to demonstrate stability of the subjects' performance over time. The repeated measures provide evidence that the gains made by 30 days persist through the 120-day interval, suggesting that the EarLens™ CHD remains effective while being worn over time.

Figure 7: Word Recognition

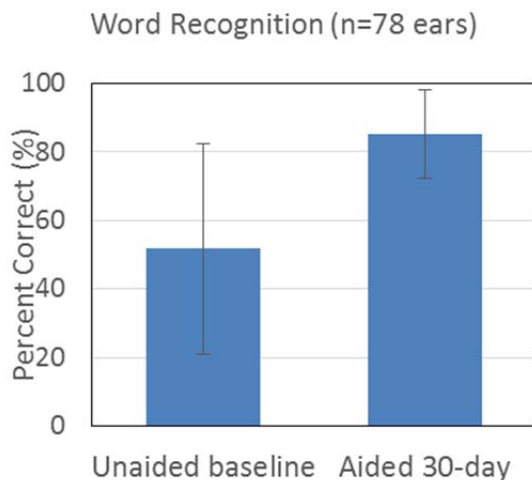
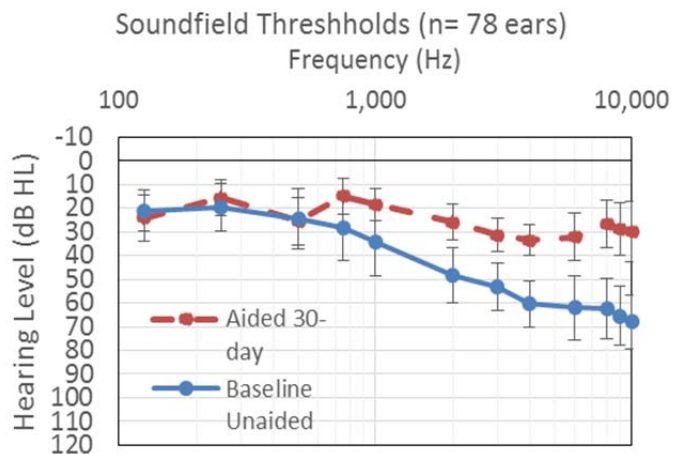


Figure 8: Soundfield thresholds



The signal processing of the EarLens™ CHD includes algorithms (Wide Dynamic Range Compression (WDRC), Fixed Directional Microphone (DDM), Environmental Noise Reduction (ENR), Dynamic Feedback Cancellation (DFC), Automatic Gain Control Output (AGCO), Sliding Bias, and dual microphone processing) that were worn by subjects throughout the study, and thus were included as part of the effectiveness outcomes and perceived benefit.

Additional effectiveness measures included speech in noise testing with the Hearing in Noise Test (HINT) and Quick SIN. The aided 30-day scores trend toward improvement but statistically significant benefit was not reached on either of these tests in the omni-directional microphone listening mode. When directionality was active, the directional microphone provided an average of 3.14 dB of benefit over the unaided baseline condition. This is a statistically significant ( $p < 0.0001$ ) and clinically meaningful improvement relative to the baseline unaided scores.

An additional measure of device effectiveness was perceived benefit as measured by the Abbreviated Profile of Hearing Aid Benefit (APHAB). The APHAB is a validated and widely used clinical tool for assessing hearing aid benefit. The APHAB was completed for the EarLens™ CHD and the subjects' own conventional hearing aids. The average baseline unaided percentage of communication difficulties was 58% (standard deviation = 16%), the percentage of difficulties decreased to 30% (standard deviation = 13%) with the subject's own air conduction hearing aid, and for EarLens™ it was 29% (standard deviation = 14%). Ninety-two percent (92%) of subjects completing the study (35 out of 38) perceived a statistically significant improvement for EarLens™ relative to unaided as measured by APHAB, based on normative data for this questionnaire.<sup>1</sup> This amount of benefit is predictive of noticeable benefit and success with amplification.<sup>1</sup> The global APHAB scores for the subjects (n=36) using their own hearing aids and the EarLens™ CHD were essentially the same (1% difference) suggesting that there was not a clinically significant difference in perception of overall benefit for the EarLens™ CHD compared to the subjects' own hearing aids as measured by APHAB.

All subjects completed a Study Exit Questionnaire (developed by EarLens™) upon exiting the study after 4 months of EarLens™ CHD wear. This is a 15 item questionnaire that asks subjects to rate their satisfaction with the EarLens™ CHD in the following domains: quality, naturalness, and clarity of sound, understanding speech in noise, ability of the device to address their hearing problems, quality of music, device comfort, cosmetics, etc. For these items, subjects were asked to select one of 6 ratings that ranged from Very Satisfied to Very Dissatisfied. In addition, the subjects were asked to rate the performance of the EarLens™ CHD in terms of how well it improved their experience in several areas (e.g., hearing in noisy environments, ability to participate in group conversations) relative to the unaided condition. Subjects were asked to select one of 5 ratings that ranged from Very Much Improved to Worse. The majority of subjects were satisfied with their ability to understand speech in noisy environments with the EarLens™ CHD (90% responded Satisfied or Very Satisfied) and found that the EarLens™ CHD improved their ability to participate in group conversations (80% responded Improved or Very Much Improved). Additionally, most subjects found that the EarLens™ CHD reduced the level of effort required to carry on conversations (87.5% responded Improved or Very Much Improved). Overall, most subjects were satisfied with the quality of sound delivered by the EarLens™ CHD (90% responded Satisfied or Very Satisfied) and found that EarLens™ CHD improved their overall quality of life (77.5% responded Improved or Very Much Improved).

<sup>1</sup>Cox, R., & Alexander, G. (1995). The abbreviated profile of hearing aid benefit. *Ear and Hearing, 16*(2), 176-186.

### Summary of Extended Study

The safety and effectiveness of the EarLens™ CHD is currently being monitored beyond the 4 months of the Definitive Study. In the Extended Study, 24 subjects (48 ears) have opted to continue wearing the device after completing the Definitive study. As of April 30, 2015, 92% of ears have 6 or more months cumulative TMT wear, 50% have 9 or more months, and 4% (2 ears) have 12 or more months of cumulative TMT wear. Of the 24 active subjects in the Extended Wear Study, 11 related AEs were experienced by 8 subjects in 10 ears. All events were temporary and resolved. Nine of 11 AEs were related to ear cleaning pre-impression (3 AEs), the

impression procedure (4 AEs), or the inspection process pre-impression (2 AE). Two of the related AEs were attributed to Ear Tip fit and both were resolved after Ear Tip modification. One subject continues to report a sensation of fullness.

Based on the results of these clinical studies, the EarLens™ CHD has been shown to be reasonably safe and effective in delivering the full spectrum of amplification from 125 Hz to 10,000 Hz for at least 4 months of wear.

**LABELING**

The sponsor provided labeling information, which includes Physician Instructions for Use, Patient Instructions for Use, and Hearing Professional Instructions for Use. In addition, the sponsor provides an Ear Impression Kit that includes instructions for the physician regarding how to obtain an ear impression for the EarLens™ CHD. Because the TMT component cannot be self-removed, a patient card is required that can be carried with the patient to provide information about the device (e.g., MR Unsafe, who should remove it, who to contact) in cases of emergency.

The labeling is sufficient and satisfies the requirements of 21 CFR 801.109 Prescription devices. The patient labeling also follows the principles identified in FDA’s guidance entitled “Medical Device Patient Labeling” (April 2001). The labeling includes a summary of the clinical studies, detailed instructions on how to fit the device to the patient, instructions for periodic cleaning of the BTE and Ear Tip, and information related to electromagnetic compatibility. In addition, the patient instructions for use includes information on how to correctly use and maintain the device, the potential risks and benefits associated with the use of the device, and alternative treatments.

**RISKS TO HEALTH**

Table 5 below identifies the risks to health that may be associated with use of tympanic membrane contact hearing aid and the measures necessary to mitigate these risks.

Table 5: Identified Risks to Health and Mitigation Methods

<b>Identified Risk</b>	<b>Mitigation Method</b>
Adverse Tissue Reactions	<ul style="list-style-type: none"> <li>• Biocompatibility</li> <li>• Labeling</li> </ul>
Electromagnetic Incompatibility	<ul style="list-style-type: none"> <li>• Non-Clinical Performance Testing</li> <li>• Labeling</li> </ul>
MRI Incompatibility	<ul style="list-style-type: none"> <li>• Labeling</li> </ul>
Overheating of Ear Canal or Skin	<ul style="list-style-type: none"> <li>• Non-Clinical Performance Testing</li> <li>• Clinical Performance Testing</li> <li>• Labeling</li> </ul>
Damage to Eyes from Direct Laser Exposure	<ul style="list-style-type: none"> <li>• Labeling</li> </ul>

Trauma/Damage to the Ear Canal, Tympanic Membrane, or Middle Ear System	<ul style="list-style-type: none"> <li>• Non-Clinical Performance Testing</li> <li>• Clinical Performance Testing</li> <li>• Training</li> <li>• Labeling</li> </ul>
Residual Hearing Loss	<ul style="list-style-type: none"> <li>• Non-Clinical Performance Testing</li> <li>• Clinical Performance Testing</li> <li>• Labeling</li> </ul>
Ear Infections	<ul style="list-style-type: none"> <li>• Clinical Performance Testing</li> <li>• Labeling</li> </ul>
Vertigo or Tinnitus	<ul style="list-style-type: none"> <li>• Clinical Performance Testing</li> <li>• Labeling</li> </ul>
Dampening of Residual Hearing When the Device Is Turned off	<ul style="list-style-type: none"> <li>• Clinical Performance Testing</li> <li>• Labeling</li> </ul>

**SPECIAL CONTROLS:**

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.

### **BENEFIT/RISK DETERMINATION**

The risks of the device are based on data collected in the clinical studies described above. The most commonly occurring adverse events were abrasions, swelling, or blood blisters in the ear canal or on the tympanic membrane (22 occurrences), and were mostly related to the ear impression procedure or insertion/removal of the Ear Tip. The risk of granulation tissue forming on the tympanic membrane was found to be minimal, with only 3 occurrences noted, and images of the tympanic membranes post-EarLens™ CHD removal use suggest that they appear healthy after 4 months of device use. The type and severity of risks associated with the EarLens™ CHD were found to be generally consistent with deep canal hearing aids. Additionally, none of the device-related adverse events reported in the clinical study were determined to be serious in nature, and there were no unanticipated adverse device effects reported. All but one of the reported adverse events was temporary in nature or resolved with minimal to no medical intervention. Unaided hearing thresholds remained stable when compared before and after 4 months of device use. There was no clinically or statistically significant decrease ( $p \leq 0.0001$ ) in hearing sensitivity (equal to or greater than 10 dB) at any frequency for the subjects, on average, nor did any single subject experience a 10 dB or greater decrease in hearing at any frequency over the course of the study. Furthermore, damping of the tympanic membrane with the TMT in place was minimal and shown to be completely reversible once the TMT was removed. This strongly supports the safety of the device related to the risk of a decrease in hearing sensitivity as a function of device use. No overheating of the ear canal was observed with the use of the laser diode transducer. Given that this device will be prescribed and monitored by a physician, there is a high likelihood that risks are mitigated and patients would typically experience only non-serious adverse events, which would be reversible by modification or removal of the device.

The probable benefits of the device are also based on data collected in the clinical studies as described above. The measured clinical benefits for these hearing impaired subjects are highlighted in the primary and secondary endpoints and served to show the device's impact on patient communication (i.e., improvement in patient function), patient satisfaction and overall improved quality of life within the target population of individuals 18 years of age and older. The EarLens™ CHD is able to provide significant and appropriate amounts of amplification for patients with mild to severe sensorineural hearing loss, especially in the high frequencies. Substantial improvements in aided thresholds (functional gain) were achieved with the EarLens™ CHD compared to the unaided levels (30.5 dB of functional gain from 2000-10000 Hz on average). Adequate amplification of this frequency region is important for audibility of speech. For some patients, this benefit in magnitude was exceptionally strong in the extended-

high frequency range (8000-10000 Hz) resulting in the benefit of increased audibility across a broad spectrum of sound. It is noted that subjects' performance with the EarLens™ CHD was only compared to without the EarLens™ CHD (unaided hearing loss) on these endpoints, and not to performance with other hearing aids. Thus, we cannot determine if there are any perceptual benefits of the EarLens™ CHD compared to the alternative treatment of conventional air conduction hearing aids for this population. The amplification provided by the EarLens™ CHD resulted in a very meaningful word recognition improvement of ~33% compared to without the device when listening at soft conversational levels (primary endpoint). This is a significant improvement and is expected to yield great benefit for hearing impaired patients in daily communication. This was reflected in an additional measure of subjective benefit on a validated scale used widely in clinical practice to document the benefit of hearing aid fittings: The Abbreviated Profile of Hearing Aid Benefit (APHAB). Subjects showed statistically and clinically significant subjective improvement in ease of communication and listening in noisy environments. An exit questionnaire showed that 90% of subjects were satisfied or very satisfied with the EarLens™ CHD.

In conclusion, given the available information above, the data support that the probable benefits outweigh the probable risks for the EarLens™ Contact Hearing Device for providing amplification of a broad range of frequencies to compensate for mild to severe sensorineural hearing loss in patients 18 years and older. The device provides substantial benefits and the risks can be mitigated by the use of general controls and the identified special controls.

## **CONCLUSION**

The *de novo* for the EarLens™ Contact Hearing Device is granted and the device is classified under the following:

Product Code: PLK

Device Type: Tympanic membrane contact hearing aid

Class: II

Regulation: 21 CFR 874.3315