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

December 29, 2015

iHear Medical, Inc.
Ms. Angela Foreman
Director, Quality Assurance & Regulatory Affairs
15250 Hesperian Blvd, Ste. #102
San Leandro, CA 94578

Re: K151025
Trade/Device Name: iHearTest
Regulation Number: 21 CFR 874.1050
Regulation Name: Audiometer
Regulatory Class: Class II
Product Code: EWO
Dated: November 17, 2015
Received: December 2, 2015

Dear Ms. Foreman:

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. 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); 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 Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151025

Device Name
iHearTest

Indications for Use *(Describe)*
The iHearTest is an air-conduction over the counter hearing screener for profiling your hearing ability based on guidelines by the World Health Organization (WHO). The iHearTest is intended for home use by adults of at least 18 years of age. Hearing test results are displayed on the computer screen and stored in our HIPAA-compliant remote server for review anytime using secure online access.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

Date Prepared: December 21, 2015

Submitter Information:

Company Name: iHear Medical Inc.

Company Address: 15250 Hesperian Blvd. Suite #102
San Leandro, CA 94578

Contact Person: Angela Lee Foreman, Ph.D., Director, QA/RA
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Device Information:

Trade Name: iHearTest

Common Name: Hearing Screener, Audiometer

Classification Name: Audiometer

Device Class/Code: Class II Exempt, EWO

Regulation Number: 21 CFR §874.1050

Type of 510(k): Traditional

Predicate Devices:

1. **Maico MA1 Handheld Audiometer**, (Establishment # 2113281) Maico Diagnostics, Exempt under 21 CFR §874.1050
2. **Earscan 3 Screening Audiometer** (K 982878) Micro Audiometric Corp.; approved for marketing on November 3, 1998
3. **InSound HandFit** (K 021867) InSound Medical, part of the InSound XT Hearing Aid and HandFit system, approved for marketing on November 19, 2002

Device Description: The iHearTest is an over the counter (OTC) hearing screener for profiling hearing ability based on guidelines by the World Health Organization (WHO). The iHearTest is intended for home use by adults of at least 18 years of age.

The iHearTest Software System consists of:

- The iHearUSB device for connection to a personal computer via USB port.
- Factory calibrated in-ear earphones, marked for right and left ears, with 3 tip sizes.
- iHearTest software application.
- Instructions and warranty information provided in the User Guide and online.
- A quick Install guide to assist in the initial software installation, registering the USB device, and initiating the iHearTest.

The iHearTest Software System requires a standard personal computer (PC) with USB port running Microsoft Windows or OS X. The iHearTest software application is a browser-based software application executed from the consumer's personal computer that provides the user interface for a hearing screening test on the PC's monitor, controls the output of test sound signals from an iHearUSB device connected to the PC's USB port, displays hearing test results and sends the results to a remote HIPAA compliant server for review anytime by the consumer using secure online access, and conducts periodic checks of earphone calibration via the calibration tool incorporated into the iHearUSB device.

The User Guide and the online instructions instruct the individual in operations and functions. The individual follows the instructions to initiate and proceed with the hearing screening procedure.

The iHearTest kit is designed to produce air-conducted sounds via the in-ear earphone within the supra-threshold range of 25-85 dB HL at test frequencies of 500, 1000, 2000 and 4000 Hz. The iHearTest software application prompts the user to respond to test sounds and determines the individual's hearing level at each test frequency. The user's overall hearing ability is then computed and displayed for both the right and left ear with a recommendation for potential hearing aid use as per WHO guidelines. The user is provided, both online and in the User Guide, with disclaimers and safety information pertaining to the iHearTest. If a contraindication exists, the consumer must submit a physician-signed Medical Clearance prior to proceeding with the hearing screening.

The iHearUSB device incorporates a microphone for sensing the background noise during the hearing screening process, and ensuring that the background noise is within an acceptable level range.

Indications for Use: The iHearTest is an air conduction over the counter hearing screener for profiling your hearing ability based on guidelines by the World Health Organization (WHO). The iHearTest is intended for home use by adults of at least 18 years of age. Hearing test results

are displayed on the computer screen and stored in our HIPAA-compliant remote server for review anytime using secure online access.

Intended Use: The online iHearTest is intended for the adult consumer to provide basic hearing screening in the convenience of home or office.

Comparison to Predicate Device: Device features and parameters are similar for the iHearTest, which is the subject of this 510(k) Notification, and the aforementioned predicate devices. The intended use (including patient population) for the iHearTest is mostly consistent with the cited predicate devices in terms of technological characteristics (i.e., design, material, and sound emissions). The iHearTest is designed for self-administration by the adult consumer; it is not a diagnostic tool for the professional health care provider.

Performance testing:

Verification testing was conducted on the iHearTest software and the iHearUSB firmware to confirm the correct functioning of the Software System as described above, including correct output of sounds at test frequencies of 500, 1000, 2000 and 4000 Hz. Even when other Windows programs/apps were running in parallel. Also manipulation of Windows audio output settings were verified to not affect the intended sound output, consistent with the design of the iHear system.

Earphones were confirmed to be factory-calibrated using industry standard calibration tools, and are confirmed to maintain calibration after simulated aging and weathering tests.

The iHearUSB device's built-in calibration tool is confirmed to have identical calibration test results as industry standard calibration tools both at the time of manufacturing and after simulated aging and weathering tests.

Engineering validation was performed to demonstrate performance in accordance with recognized standards for this type of device, namely ANSI S3.6-2010 Type 4 air-conduction audiometer and the World Health Organization (WHO) guidelines for determination of hearing impairment.

Clinical Study Summary:

An Institutional Review Board (IRB)-approved clinical study was conducted to assess the safety and efficacy of the iHearTest as a home air-conduction hearing screener. The study included 96 subjects (192 ears): 54 males and 42 females, ages 22-90 years with median age of 52. The iHearTest scoring results were compared to World Health Organization (WHO) grading of hearing impairment using standard practice audiometry. The study targeted adult subjects with known or suspected hearing loss. The primary objective of the iHearTest clinical study was to determine identification of disabling hearing impairment (corresponding to WHO levels 2-4), and the extent to which the iHearTest agreed with the WHO method for determining hearing impairment. The clinical study results showed 96.4% agreement with the WHO method using

standard practice audiometry for the assessment of disabling hearing impairment, with sensitivity and specificity of 95% and 97%, respectively. For the ordinal assessment of hearing ability, the iHearTest showed 85.9% level-by-level (WHO grades of 0-4) agreement and 100% agreement within ±1 level with respect to WHO grading using standard practice instruments. The 14.1% variability in ordinal assessment for the iHearTest with respect to the standard practice method was consistent with the 13.5% variability across two standard practice audiometry methods evaluated in the study.

In addition to determining agreement with the WHO method using standard practice audiometry, the usability of the iHearTest system was also evaluated to obtain comments on the subjective experience with the iHearTest device, its packaging, software installation and setup. The iHearTest was found to be safe and effective as an over-the-counter hearing screening device.

In summary, subjects tested included both male and female adult participants, of the appropriate age range, and varied hearing impairment levels (i.e., subjects with normal hearing and mild to severe impairment). No adverse effects or complications were observed. The performance data collected supports a substantial equivalence determination.

Safety: The design of the iHearTest device provides safety to the individual user. To prevent the unlikely possibility of excessive exposure to high-level sound, hardware and software were implemented to limit maximum sound output to below 90 dB HL. The iHearTest device has been designed to conform to the following performance and safety standards:

ANSI S3.6-2010	Specifications for Audiometers, American National Standards Institute
EN/IEC 60601-1	Medical electrical equipment: Part 1: General requirements for safety
EN/IEC 60601-1-2	Medical electrical equipment: Part 1: General requirements for safety; Section 1-2 Collateral standard: Electromagnetic compatibility - Requirements and tests

Conclusion: The information and data provided in this 510(k) Notification establish that the iHearTest device with the online test performed by the consumer using his/her home computer is substantially equivalent to the aforementioned legally marketed predicate devices.