July 15, 2019

Interacoustics A/S
Erik Nielsen
Director, Regulatory & Compliance
Audiometer Alle 1
Middelfart, DK-5500 Dk

Re: K191372
Trade/Device Name: Lyra
Regulation Number: 21 CFR 874.1050
Regulation Name: Audiometer
Regulatory Class: Class II
Product Code: EWO
Dated: May 13, 2019
Received: May 22, 2019

Dear Erik Nielsen:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Srinivas Nandkumar, Ph.D.
Assistant Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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)*
K191372

Device Name
Lyra

Indications for Use *(Describe)*
The Lyra with DPOAE is intended for use in the audiologic evaluation and documentation of ear disorders using Distortion Product Otoacoustic Emissions. The target population for Lyra with DPOAE includes all ages.

The Lyra with TEOAE is intended for use in the audiologic evaluation and documentation of ear disorders using Transient Evoked Otoacoustic Emissions. The target population for Lyra with TEOAE includes all ages.

The Lyra System is to be used by trained personnel only, such as audiologists, ENT surgeons, doctors, hearing healthcare professionals or personnel with a similar level of education. The device should not be used without the necessary knowledge and training to understand its use and how results should be interpreted.

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.

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FDA 510(k) K191372 Lyra
Summary as required by 21 CFR 807.92.

Administrative Information

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Contact Person: Erik Nielsen
Director of Regulatory Affairs
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Date Summary Prepared: May 13, 2019

Device Identification

Trade Name: Lyra™
Common Name: audiometry, otoacoustic emission device
Device Classification Name: Audiometer
Device classification: Class II
Panel: Ear Nose & Throat
Classification Regulation: 874.1050
Product Code: EWO

Primary Predicate Device: Titan™(TEOAE), cleared on 06/20/2013 via K130795

Secondary Predicate Device: Titan™(DPOAE), cleared on 05/05/2011 via K103760

Device Description

The device is audiometric equipment used for assisting in detecting of inner ear abnormalities. Lyra features a hardware unit connecting to a PC installed with IA OAE suite software designated for use with Lyra. The PC software provides a user interface designed to integrate in the standard Microsoft Windows environment. Lyra can be purchased with various licenses allowing you to perform different hearing screening tests.

Distortion product otoacoustic emissions (DPOAE) technology uses pairs of pure tones presented in sequence to screen patients for cochlear hearing loss. Responses to the stimulus are predictable and therefore can be measured via a sensitive microphone placed in the patient's ear canal.

Transient otoacoustic emissions (TEOAE) technology uses a short duration stimulus to screen patients for cochlear hearing loss. Responses to the stimulus are predictable and therefore can be measured via a sensitive microphone placed in the patient's ear canal. The response can be divided into frequency bands for assessment.

Device Intended Use / Device indications for use

The Lyra with DPOAE is intended for use in the audiologic evaluation and documentation of ear disorders using Distortion Product Otoacoustic Emissions. The target population for Lyra with DPOAE

includes all ages.

The Lyra with TEOAE is intended for use in the audiologic evaluation and documentation of ear disorders using Transient Evoked Otoacoustic Emissions. The target population for Lyra with TEOAE includes all ages.

The Lyra System is to be used by trained personnel only, such as audiologists, ENT surgeons, doctors, hearing healthcare professionals or personnel with a similar level of education. The device should not be used without the necessary knowledge and training to understand its use and how results should be interpreted.

Technological Characteristics

Lyra features a hardware unit connecting to a PC installed with IA OAE suite software designated for use with Lyra. Power to the Lyra is provided from the USB connection to the PC.

A comparison between the new and predicate devices shows that the technological characteristics and indications for use are equivalent. The device employs similar technology to accomplish the same tasks as the predicates. A detailed table is provided below.

Equivalence Predicate Chart 1 (primary):

Description	Titan with TEOAE440 (k130795)	Lyra
Type	Audiometer – Audiometric equipment	Same
Regulation Number	21 CFR 874.1050 (otoacoustic emission device)	Same
Classification Product Code	EWO	Same
Indications for Use	The Titan with TEOAE440 is intended for use in the audiologic evaluation and documentation of ear disorders using Transient Evoked Otoacoustic Emissions.	Same
Target Population	The devices are suitable for all populations including new-born infants	Same
Intended User	The Titan System is to be used by trained personnel only such as audiologists, ENT surgeons, doctors, hearing healthcare professionals or personnel with a similar level of education.	Same (or used by a trained technician under the supervision of a professional)
Anatomical Sites	Examination of Ear	Same
Safety Standards	IEC 60601-1	Same
Performance Standards	IEC 60645-6	Same
Device Type	Screening and diagnostic	Same
System Configuration	Dedicated hardware unit with no display or controls. OAE probe permanently connected to hardware unit. Hardware unit operated through a connected PC.	Same for clinical use. (Titan also has possibility for handheld use as it also has display and controls on device)
TEOAE Stimulus		
Frequency Range	500 to 5500Hz	same

Stimuli Type	Non-Linear and Linear Short duration signal According to IEC 60645-3	same
Level	30 to 90 dB peSPL	same
Level Step	1 dB SPL	same
Transducer	Dedicated OAE Probe	same
Probe Detection	Auto detection	same
Recording		
A/D Resolution	24 bit	same
Artifact Reject System	0 -> +60 dB SPL or off	same
Automatic test with display of PASS-REFER	Yes	same

Equivalence Predicate Chart 2 (secondary):

Description	Titan With DPOAE440 (k103760)	Lyra
Type	Audiometer – Audiometric equipment	Same
Regulation Number	21 CFR 874.1050 (otoacoustic emission device)	Same
Classification Product Code	EWO	Same
Indications for Use	The Titan with DPOAE440 is intended for use in the audiologic evaluation and documentation of ear disorders using Distortion Product Otoacoustic Emissions.	Same
Target Population	The devices are suitable for all populations including new-born infants	Same
Intended User	The Titan System is to be used by trained personnel only such as audiologists, ENT surgeons, doctors, hearing healthcare professionals or personnel with a similar level of education.	Same (or used by a trained technician under the supervision of a professional)
Anatomical Sites	Examination of Ear	Same
Safety Standards	IEC 60601-1	Same
Performance Standards	IEC 60645-6	Same
Device Type	Screening and diagnostic	Same
System Configuration	Dedicated hardware unit with no display or controls. OAE probe permanently connected to hardware unit. Hardware unit operated through a connected PC.	Same for clinical use. (Titan also has possibility for handheld use as it also has display and controls on device)
DPOAE Stimulus		
Frequency range (f2)	500Hz – 10kHz	Same
Stimuli Type	2 pure tones	same
Level	30 dB SPL to 80 dB SPL	Same
Level Step	1 dB SPL	same
Transducer	Dedicated OAE Probe	same
Probe Detection	Auto detection	same
Recording		
A/D Resolution	24 bit	same

Artifact Reject System	0 -> +60 dB SPL or off	same
Automatic test with display of PASS-REFER	Yes	same

Summary of Non-Clinical Testing

Design verification and validation were performed according to current standards for OAE to assure the device meets its performance specifications. EMC and Safety was performed in compliance with recognized standards IEC 60601-1 series, Medical Electrical Equipment – General requirements for basic safety and essential performance. The product meets the requirements from the international standard for OAE measurements IEC 60645 series. Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in medical Devices." The software for this device was considered as a "minor" level of concern since a malfunction of, or a latent design flaw in, the Software Device could not lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury. Internal validation and comparison tests were performed and demonstrate that Lyra fulfil the requirements and is valid for its intended medical purpose.

Summary of Clinical Testing

Not applicable. Not required to establish substantial equivalence.

Conclusion

We have compared the intended use and performance characteristics with the predicate device. The Lyra was tested according to current standards and there were found no significant differences between the devices.

The Lyra conforms to the current standards. After analyzing bench testing, safety, EMC, and software validation (with risk analysis) testing we conclude that the Lyra is found to be substantially equivalent to the predicate devices in technological characteristics and indications for use.