February 14, 2018

Interacoustics A/S
Amy Yanta
Director of Regulatory Affairs
Audiometer Alle 1
Middelfart, 5500 Dk

Re: K173567
Trade/Device Name: Sera™
Regulation Number: 21 CFR 874.1050
Regulation Name: Audiometer
Regulatory Class: Class II
Product Code: EWO, GWJ
Dated: November 20, 2017
Received: November 20, 2017

Dear Amy Yanta:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely yours,

Eric A. Mann -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173567

Device Name
Sera™

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

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

The Sera™ with ABRIS is intended for use in the audiologic evaluation and documentation of ear and nerve disorders using auditory evoked potentials from the inner ear, the auditory nerve and the brainstem. The target population for Sera with ABRIS is newborns.

The Sera™ 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) K173567 Sera
Summary as required by 21 CFR 807.92.

Administrative Information

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Date Summary Prepared: August 25, 2017

Device Identification

Trade Name: Sera™
Common Name: otoacoustic emission device/evoked response auditory stimulator and measurements
Device Classification Name: Audiometer/Stimulator, Auditory, Evoked Response
Device classification: Class II
Panel: Ear Nose & Throat / Neurology
Classification Regulation: 874.1050/882.1900
Product Code: EWO/GWJ

Predicate Device: easyScreen, cleared on 08/29/2017 via K171506

Device Description

The device is audiometric equipment used for assisting in detecting of inner ear and auditory brainstem abnormalities.

Sera™ features a touch-screen display and user-friendly software in a compact hardware design. Sera™ can be purchased with various licenses allowing you to perform different hearing screening tests.

Sera™ uses auditory brainstem response (ABRIS) technology to screen patients for hearing loss. A modified click stimulus, the CE-Chirp®, of 35 dB nHL is delivered into the patient's ear while electrodes placed on the patient's head measure EEG activity.

Auditory brainstem response (ABRIS) test produces a short acoustic stimulus and measures via transcutaneous electrodes the auditory evoked potentials from the inner ear, the auditory nerve and the brainstem.

The EEG is processed and analyzed automatically using the Sera™'s response detection algorithm. When a response is detected, the screening is stopped automatically and a Pass result is assigned to the test ear. When no response is detected after 3 minutes of EEG activity has been processed, a Refer result is assigned.

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 click 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

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

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

The Sera™ with ABRIS is intended for use in the audiologic evaluation and documentation of ear and nerve disorders using auditory evoked potentials from the inner ear, the auditory nerve and the brainstem. The target population for Sera™ with ABRIS is newborns.

The Sera™ 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

The Sera™ consists of a handheld unit that utilizes a touchscreen display and a rechargeable battery. A simple cradle is included to support charging of the device's battery. The device supports Bluetooth communication with a label printer for the purpose of printing screening results.

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:

Description	Predicate: easyScreen (K171506)	Device: Sera™
Type	Audiometer/ Auditory Brainstem Response – Audiometric equipment	Audiometer/ Auditory Brainstem Response – Audiometric equipment

Regulation Number	21 CFR 874.1050 (otoacoustic emission device) 21 CFR 882.1900 (Evoked response auditory stimulator)	21 CFR 874.1050 (otoacoustic emission device) 21 CFR 882.1900 (Evoked response auditory stimulator)
Classification Product Code	EWO, GWJ	EWO, GWJ
Regulatory Class	Class II	Class II

Indications for Use	The device DPOAE and TEOAE modules are intended for use in the audiologic evaluation and documentation of ear disorders using Distortion Product Otoacoustic Emissions or Transient Otoacoustic Emissions technology. The target population for the modules includes all ages. The device ABR module is intended for use in the audiologic evaluation and documentation of ear and nerve disorders using auditory evoked potentials from the inner ear, the auditory nerve and the brainstem. The target population for the ABR module is newborns and infants up to 6 months of age.	The Sera™ with DPOAE is intended for use in the audiologic evaluation and documentation of ear disorders using Distortion Product Otoacoustic Emissions. The target population for Sera™ with DPOAE includes all ages. The Sera™ with TEOAE is intended for use in the audiologic evaluation and documentation of ear disorders using Transient Evoked Otoacoustic Emissions. The target population for Sera™ with TEOAE includes all ages. The Sera™ with ABRIS is intended for use in the audiologic evaluation and documentation of ear and nerve disorders using auditory evoked potentials from the inner ear, the auditory nerve and the brainstem. The target population for Sera™ with ABRIS is newborns. The Sera™ 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. The intended use differs slightly because the Sera separates each function's intended use instead of grouping.
Target Population	The devices are suitable for all	The devices are suitable for all

	populations including new-born infants. The patient group includes all ages and sexes.	populations including new- born infants. The patient group includes all ages and sexes.
Intended User	The easyScreen 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. (or trained user with supervision of a professional)	The Sera™ 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. Intended user specifies further intended user.
Anatomical Sites	Examination of Ear and hearing nerves	Examination of Ear and hearing nerves
Safety Standards	IEC 60601-1	IEC 60601-1
Performance Standards	IEC 60645-7, IEC 60645-6	IEC 60645-7, IEC 60645-6
Device Type	Screening device (PASS/REFER)	Screening device (PASS/REFER)
System Configuration	1 -channel ABR system operated through a handheld base unit. The base unit is operated as a stand alone device	1 -channel ABR system operated through a handheld base unit. The base unit is operated as a stand alone device
Display Information	Noise status, detected transducer, artifact %, PASS/REFER status	Noise status, detected transducer, artifact %, PASS/REFER status
Stimulus	Clicks and chirps, pure tones	Clicks and chirps, pure tones
Electrode Quality Check	Yes	Yes
Impedance Test	acceptable impedance <40kOhm.	acceptable impedance <40kOhm.
Binaural screening	Yes	Yes
Pre-amplifier channels	1	1
Stimulus Rate	90/s	90/s
Pre-amplifier Gain	ABRIS - 64 dB (fixed) + 64dB (Variable)	ABRIS - 72dB The higher dB allows for a higher ceiling of sound to be exported from sound source
Stimulus Level	ABR - 30, 40 and 45db nHL/ DPOAE -30 dB SPL to 80 dB SPL	ABR - 30, 40 and 45db nHL/ DPOAE -30 dB SPL to 80 dB SPL
Masking	NONE	NONE
Transducers	OAE probe, RadioEar IP30 insert earphone	OAE probe, RadioEar IP30 insert earphone
Frequency range (f2)	DPOAE 500Hz – 10kHz	DPOAE 500Hz – 10kHz
TEOAE Stimulus		
Frequency Range	500 to 5500Hz	500 to 5500Hz

Stimuli Type	Non-Linear and Linear Short duration signal (Click) According to IEC 60645-3	Non-Linear Short duration signal (Click) According to IEC 606045-3 Default is only Non-linear
Level	30 to 90 dB peSPL	30 to 90 dB peSPL
Level Step	1 dB SPL	1 dB SPL
Transducer	Dedicated OAE Probe	Dedicated OAE Probe
Probe Detection	Auto detection	Auto detection
Recording		
A/D Resolution	24 bit	24 bit
Artifact Reject System	0 -> +60 dB SPL or off	0 -> +60 dB SPL or off
Automatic test with display of PASS-REFER	Yes	Yes

Summary of Non-Clinical Testing

Design verification and validation were performed according to current standards for OAE and ABR 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 "moderate" level of concern since a malfunction of, or a latent design flaw in, the Software Device could lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury. The OAE and ABRIS measurements were divided into 3 phases. Phase 1 included when optimization occurred and involved feedback to the operator so that they could adjust such as probe fit, electrode impedance, ambient electrical and acoustic noise etc. Once the pre-test conditions were optimized, phase 2 of data collection proceeded as rapid as possible to allow the maximum quantity of good quality data to be collected in the shortest possible time. Phase 3 proceeded into the data assessment and decision stage and this ran concurrently with Phase 2 once the predetermined minimum amount of data had been collected. Phase 3 then went into the algorithm descriptions for each TEOAE, DPOAE and ABRIS measurements modes and is provided in detail in Annex 16D of this submission. No clinical tests were performed, but based on the fulfillment of the international standards for OAE and ABR we believe the device is safe and effective. The auditory impedance testing characteristics and safety systems were compared and found to be comparable.

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 Sera™ was tested according to current standards and the differences found between the devices were related to functionality, not in relation to safety and efficiency. The Sera™ conforms to the current standards. After analyzing bench testing, safety, EMC, and software validation (with risk analysis) testing we conclude that the Sera™ is found to be substantially equivalent to the predicate devices in technological characteristics and indications for use.