April 24, 2020

Grason-Stadler Inc.
% Daniel Kamm
Principal Engineer
Kamm & Associates
8870 Ravello Ct.
Naples, Florida 34114

Re: K193033
Trade/Device Name: GSI Audera Pro
Regulation Number: 21 CFR 882.1900
Regulation Name: Evoked Response Auditory Stimulator
Regulatory Class: Class II
Product Code: GWJ
Dated: March 27, 2020
Received: March 31, 2020

Dear Daniel Kamm:

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,

Jay Gupta
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine 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)*
K193033

Device Name
GSI Audera Pro

Indications for Use *(Describe)*
The Audera Pro is intended to be used for the stimulation, recording and measurement of auditory evoked potentials, vestibular evoked myogenic potentials, auditory steady state responses and otoacoustic emissions. The device is indicated for use in the evaluation, identification, documentation and diagnosis of auditory and vestibular disorders. The device is intended to be used on patients of any age.

The Audera Pro is intended to be used by qualified medical personnel such as an audiologist, physician, hearing healthcare professional, or trained technician. The Audera Pro is intended to be used in a hospital, clinic, or other healthcare facility with a suitable quiet testing environment.

The anatomical sites of contact for auditory evoked potential (AEP) testing are the patient's ear canal (with the contact object being a sound delivery eartip or headphone, or an ear probe and eartip) and the patient's scalp and possibly other body sites (with the contact object being a bone transducer or electrodes that are capable of measuring bio-potentials). The anatomical sites of contact for vestibular evoked myogenic potential (VEMP) testing are the patient's ear canal (with the contact object being a sound delivery eartip or headphone, or an ear probe and eartip) and the patient's head and neck and possibly other body sites (with the contact object being a bone transducer or electrodes that are capable of measuring bio-potentials). The anatomical sites of contact for otoacoustic emission (DPOAE, TEOAE) testing are the patient's ear canal (with the contact object being an ear probe and eartip).

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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510(K) Summary

I. SUBMITTER

Grason-Stadler Inc.
10395 West 70th Street
Eden Prairie, MN 55344

Tel: 952 278-4402

Contact Person: Brent Nissly, General Manager/COO
Date Prepared: February 28, 2020

II. DEVICE

Name of Device: GSI Audera Pro™
Common or Usual Name: Audera Pro
Classification Name: Evoked Response Auditory Stimulator (21 CFR 882.1900)
Regulatory Class: Class II
Product Code: GWJ

III. PREDICATE DEVICE

K163326, Predicate for: Hardware platform for all modules, Software platform for VEMP and AEP modules
Manufacturer: Intelligent Hearing Systems
Trade/Device Name: SmartEP (Duet platform)
Classification Name: Evoked Response Auditory Stimulator (21 CFR 882.1900)
Regulatory Class: Class II
Product Code: GWJ, GWF, GWE, ETN

K061443, Predicate for: ASSR, DPOAE, and TEOAE modules
Trade/Device Name: Smart USBLite (with SmartEP, SmartScreener, SmartOAE, SmartTrOAE, & SmartEP-ASSR)
Classification Name: Audiometer (21CFR 874.1050)
Regulatory Class: Class II
Product Code: GWJ; EWO; GWL

IV. DEVICE DESCRIPTION

The device is a configurable platform used to aid in the screening and diagnosis of sensory-neural and hearing conditions. It is capable of performing the following procedures: Auditory Evoked Potentials (EP), Auditory Steady-State Response (ASSR), Distortion Products Otoacoustic Emissions (DPOAE), Transient Evoked Otoacoustic Emissions (TEOAE), and vestibular evoked myogenic potentials (VEMP). The device system consists of a laptop PC with Windows 10 Pro, placed on top of or beside a specialized hardware implementation interface (i.e. platform) for the procedures. Software in the laptop controls the specialized hardware and collects and analyzes the resulting signals. Transducers and various accessories connect to the specialized hardware via connectors on the back of the hardware package.

V. INDICATIONS FOR USE

The Audera Pro is intended to be used for the stimulation, recording and measurement of auditory evoked potentials, vestibular evoked myogenic potentials, auditory steady state responses and otoacoustic emissions. The device is

indicated for use in the evaluation, identification, documentation and diagnosis of auditory and vestibular disorders. The device is intended to be used on patients ofany age.

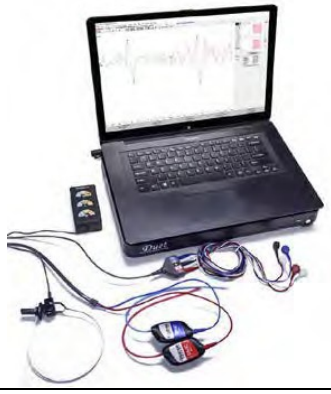
The Audera Pro is intended to be used by qualified medical personnel such as an audiologist, physician,hearing healthcare professional, or trained technician. The Audera Pro is intended to be used in a hospital, clinic, or other healthcare facility with a suitable quiet testing environment. The anatomical sites of contact for auditory evoked potential (AEP) testing are the patient's ear canal (with the contact object being a sound delivery eartip or headphone, or an ear probe and eartip) and the patient's scalp and possibly other body sites (with the contact object being a bone transducer or electrodes that are capable of measuring bio-potentials).

The anatomical sites of contact for vestibular evoked myogenic potential (VEMP) testing are the patient's ear canal (with the contact object being a sound delivery eartip or headphone, or an ear probe and eartip) and the patient's head and neck and possibly other body sites (with the contact object being a bone transducer or electrodes that are capable of measuring bio-potentials). The anatomical sites of contact for otoacoustic emission (DPOAE, TEOAE) testing are the patient's ear canal (with the contact object being an ear probe and eartip)

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The following technological differences exist between the GSI Audera Pro™ MEG and the predicate devices. In addition, changes made to the USB Jr. Duet hardware platform include:

- Changes to the connectors on the chassis have been changed to mate with accessories;
- Changes to the equalization circuit for the OAE probe to match probe model; and
- Reduction of earphone and bone vibrator impedance (from 300 to 10Ω)

	Predicate for AEP and VEMP: K163326 **Predicate for ASSR, DPOAE, and TEOAE:** K061443	**Audera Pro:** K193033
Photo		

	Predicate for AEP and VEMP: K163326 **Predicate for ASSR, DPOAE, and TEOAE:** K061443	**Audera Pro:** K193033
Indications for Use:	**SmartEP** is an evoked response testing and diagnostic device, that is capable of eliciting, acquiring, and measuring auditory, somatosensory, visual, and vestibular evoked myogenic potential data, as well as providing nerve stimulation and monitoring. The intended use of the SmartEP device is to objectively record evoked responses from patients of all ages upon the presentation of sensory stimuli. The product is indicated for use as a diagnostic aid and adjunctive tool in sensory related disorders (i.e., auditory, somatosensory, visual, and vestibular) and in surgical procedures for inter-operative nerve monitoring. The SmartEP system is intendedto be used by trained personnel in a hospital, nursery, clinic, audiologist's, EP technologist's, surgeon's, or physician's office, operating room, or other appropriate setting. The intended use of the **Smart USBLite** device system is for the recording of auditory evoked potential, otoacoustic emissions, & auditory steady-state evoked potential data. The product is intended to be used as a diagnostic aid in auditory and hearing related disorders, as an objective measure of cochlear function, and as an adjunctive tool in the estimation of behavioral hearing thresholds on patients of all ages	The Audera Pro is intended to be used for the stimulation, recording and measurement of auditory evoked potentials, vestibular evoked myogenic potentials, auditory steady state responses and otoacoustic emissions. The device is indicated for use in the evaluation, identification, documentation and diagnosis of auditory and vestibular disorders. The device is intended to be used on patients of any age. The Audera Pro is intended to be used by qualified medical personnel such as an audiologist, physician, hearing healthcare professional, or trained technician. The Audera Pro is intended to be used in a hospital, clinic, or other healthcare facility with a suitable quiet testing environment. The anatomical sites of contact for auditory evoked potential (AEP) testing are the patient's ear canal (with the contact object being a sound delivery eartip or headphone, or an ear probe and eartip) and the patient's scalp and possibly other body sites (with the contact object being a bone transducer or electrodes that are capable of measuring bio-potentials). The anatomical sites of contact for vestibular evoked myogenic potential (VEMP) testing are the patient's ear canal (with the contact object being a sound delivery eartip or headphone, or an ear probe and eartip) and the patient's head and neck and possibly other body sites (with the contact object being a bone transducer or electrodes that are capable of measuring bio-potentials). The anatomical sites of contact for otoacoustic emission (DPOAE, TEOAE) testing are the patient's ear canal (with the contact object being an ear probe and eartip). **DIFFERENCE**: Does not support Somatosensory and Visual Evoked Potential and Nerve Stimulation modules
Tests Performed/ Associated predicate Clearance	• AEP Auditory Evoked Potentials **K163326** • ASSR Auditory Steady-State Response **K061443** • VEMP Vestibular Evoked Myogenic Potential **K163326** • TEOAE Transient Evoked Otoacoustic Emissions **K061443** • DPOAE Distortion Products Otoacoustic Emissions **K061443** Plus: The SEP, VEP, and nerve stimulation	• AEP Auditory Evoked Potentials **K163326** • ASSR Auditory Steady-State Response **K061443** • VEMP Vestibular Evoked Myogenic Potential **K163326** • TEOAE Transient Evoked Otoacoustic Emissions **K061443** • DPOAE Distortion Products Otoacoustic Emissions **K061443** **DIFFERENCE**: Does not support Somatosensory and Visual Evoked Potential and Nerve Stimulation modules

	Predicate for AEP and VEMP: K163326 **Predicate for ASSR, DPOAE, and TEOAE:** K061443	**Audera Pro:** K193033
Configuration	PC-based system with external hardware platform and external hardware peripherals (USB interface)	SAME
Hardware Implementation	PC-based system with external hardware platform and peripherals (USB interface)	SAME
Technological Characteristics		
Preamplifier/ Amplifier	Gain: 5K to 200K (8 steps) HPF cutoffs: 0.1 Hz to 300 Hz (8 steps) LPF cutoffs: 30 Hz to 500 Hz (8 steps) Impedance test capable	SAME
EEG Amplifier Channels	TWO	SAME
Stimulator Frequencies (In Hz)	125, 250 500 750 1000 2000 3000 4000 6000 8000, 16,000, Tone Burst, Click	SAME
Stimulator transducers	Headphones Insert Earphones Bone Conductor Probe Ear Tips	SAME
Patient electrode	Self stick single use disposable	SAME
OAE Probe	Two channels of acquisition; Two speakers	One channel of acquisition; One speaker **DIFFERENCE**: Can perform same testing, but with each ear individually
Interface Connectors	Headphones DIN Bone oscillator DIN Speakers DIN OAE Probe DIN Patient Connection 6 pin custom USB: USB A	Headphones 2 x ¼ inch phone (**DIFFERENCE)** Bone oscillator 1 x ¼ inch phone (**DIFFERENCE)** Speakers 2 x RCA phono (**DIFFERENCE)** OAE Probe HDMI (**DIFFERENCE)** Patient Connection 6 pin custom (SAME) USB: USB A (SAME)
Data Acquisition	Sampling Rate 40 kHz A/D resolution 16 bit	SAME
Filtering and Artifact Rejection		
Artifact Rejection	User Selectable – 0-100%	SAME
Filter Slope	- 6 dB/Octave	SAME
Notch Filter	User Selectable, 50/60 Hz	SAME

	Predicate for AEP and VEMP: K163326 **Predicate for ASSR, DPOAE, and TEOAE:** K061443	**Audera Pro:** K193033
Noise Level	≤ 0.27 µV RMS	SAME
Input Impedance	> 10 MΩ	SAME
Common Mode Rejection Ratio	≥ 110 dB @ 1 kHz, 50/60 Hz	SAME
Auditory Stimuli		
Transducers	headphones, insert earphones, bone vibrator, OAE probe, speakers	SAME
Types	Clicks, Tones, Chirps	SAME
Duration	100 µsec click default, adjustable; Tones adjustable to 500 msec	SAME
Envelopes	Rectangular, Hann, Blackman, and Gaussian, Trapezoidal, Extended Cosine, Barlett, Cosine Cubed, Exact Blackman	Rectangular, Hann, Blackman, and Gaussian, Trapezoidal, Extended Cosine **DIFFERENCE**: Does not include Barlett, Cosine Cubed and Exact Blackman envelopes
Intensity	150 dB attenuator range	SAME
Repetition Rate	0.1-100/sec	SAME
Test Frequencies	125Hz to 16kHz	125Hz to 12kHz **DIFFERENCE**: Shorter frequency range
Presentation	Right, Left, Both	SAME
Polarity	Rarefaction, Condensation, Alternating	SAME
Masking	White Noise	SAME
Analysis/Measurement Parameters		
Sweeps	1-34463	SAME
Analysis Window	-2.5 sec to +2.5 sec (maximum)	SAME
Artifact Rejection Threshold	1 – 2000 µV	SAME
Other		
Size/Weight	Main hardware unit (includes internal preamplifier): 25.00cm x 38.20cm x 4.76cm 1.13kg (2.50 lbs)	Main hardware unit (includes internal preamplifier): 29.5 x 37.3 x 6.7 cm (L x W x H) Weight 2 kg (4.4 lbs) **DIFFERENCE**: Size/weight

	Predicate for AEP and VEMP: K163326 **Predicate for ASSR, DPOAE, and TEOAE:** K061443	**Audera Pro:** K193033
Computer Operating System	Windows 10 Pro	SAME
Power	AC line	SAME
Display	Laptop LCD	SAME
Data Display	Single/split screen, multiple pages	SAME

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Testing/Evaluation Performed	Objective of Testing/Evaluation	Product Design Requirements Evaluated	Standards used for Testing/Evaluation (as applicable)
Electrical Safety (ES) and Electromagnetic compatibility (EMC)	**ES**: Demonstrate that the basic safety and essential performance requirement of the device are satisfied to ensure safe use **EMC**: Demonstrate that the basic safety and essential performance of the device is maintained in the presence of electromagnetic disturbances	**ES**: Electrical leakage, insulation, safety of applied parts **EMC**: Conducted and Radiated Emissions (CISPR 11) Electrostatic Discharge (IEC 61000-4-2) Radiated Susceptibility (IEC 61000-4-3) Transient Susceptibility (IEC 61000-4-4) Surge Susceptibility Test (IEC 61000-4-5) Conducted Immunity (IEC 61000-4-6) Power Magnetics Field (IEC 61000-4-8) Voltage Fluctuations (IEC 61000-4-11) Flicker (IEC 61000-3-3)	**ES**: IEC 60601-1: 2005 (Third Edition) + CORR.1 (2006) + CORR.2 (2007+ AMI1 (2012)) (or IEC 60601-1: 2012 reprint): Medical electrical equipment – Part 1: General Requirements for basic safety and essential performance **EMC**: IEC 60601-1-2: 2015: Medical electrical equipment – Part 1-2: General Requirements for basic safety and essential performance – Collateral Standard: Electromagnetic Disturbances - Requirements and Tests.
Electromyographs (EMG)	Demonstrate that the basic safety and essential performance for electromyographs (myofeedback equipment, as supported by the device system) is maintained	Marking, electrical and mechanical hazards, excessive temperatures, accuracy of controls and instruments and protection against hazardous outputs, stimulators default to off on electrical interruption	IEC 60601-2-40: 2016: Medical electrical equipment – Part 2-40: Particular Requirements for the Safety of Electromyographs and Evoked Response Equipment. Used in conjunction with IEC 60601-1: 2005, CORR1: 2006, CORR2: 2007, AMD1: 2012
Calibration and Test Signal	**IEC 60645-1**: Demonstrate that the device satisfies general requirements with respect to determining hearing threshold levels,	Audiometric requirements as specified by referenced standards Transducers evaluated (IEC 60645-3 & ISO 389-6):	IEC 60645-1: 2001: Electroacoustics - Audiometric equipment - Part 1: Equipment for pure-tone and speech

Testing/Evaluation Performed	Objective of Testing/Evaluation	Product Design Requirements Evaluated	Standards used for Testing/Evaluation (as applicable)
	relative to standard reference threshold levels established by means of psychoacoustic test methods **IEC 60645-3**: Ensure that audiometric stimuli of short duration are specified and measured in same way, and that calibration of the device using such signals is carried out using defined methods **ISO 389-2 and ISO 389-6**: Evaluate the ability to accurately generate calibration and test signals	• Radio Ear DD45 Supra Aural Headset • Radio Ear IP30 Insert Phones • Radio Ear B81 Bone Vibrator • Radio Ear SP90A • Free Field speaker system	audiometry IEC 60645-3:2007: Electroacoustics - Audiometric equipment - Part 3: Test signals of short duration ISO 389-2:1994: Acoustics - Reference zero for the calibration of audiometric equipment - - Part 2: Reference equivalent threshold sound pressure levels for pure tones and insert earphones ISO 389-6:2007: Acoustics - Reference zero for the calibration of audiometric equipment -- Part 6: Reference threshold of hearing for test signals of short duration
Otoacoustic emissions (OAE)	Ensure that measurements made under comparable test conditions are consistent, with respect to methods for testing and routine calibration for measurement of otoacoustic emissions	Required frequencies and amplitudes, harmonic distortion, accuracy of measurements. Presentation of results for TEOAE and DPOAE, marking requirements	IEC 60645-6: 2009: Electroacoustics - Audiometric equipment - Part 6: Instruments for the measurement of otoacoustic emissions
EP (ABR)	Ensure that measurements made under comparable test conditions are consistent, with	Measuring system, stimulus types, test quality assuring system (i.e. impedance check, artifact rejection, presentation of results, instrument marking, safety, frequency accuracy, hearing level control linearity, stimulus pulse, SPL accuracy levels, maximum transducer output level. Transducers evaluated: • Radio Ear DD45 Supra Aural Headset	IEC 60645-7: 2009: Electroacoustics - Audiometric equipment - Part 7: Instruments for the measurement of

Testing/Evaluation Performed	Objective of Testing/Evaluation	Product Design Requirements Evaluated	Standards used for Testing/Evaluation (as applicable)
	respect to characteristics and performance requirements for measurement of auditory evoked potential from the inner ear, auditory nerve and brainstem, evoked by acoustic stimuli of short duration	• Radio Ear IP30 Insert Phones • Radio Ear B81 Bone Vibrator • Radio Ear SP90A Free Field speaker system	auditory brainstem responses
Usability	To demonstrate that process used to analyze, specify, design, verify and validate usability as it relates to basic safety and essential performance of the device is in compliance with the IEC 62366 standard,	Usability Requirements, with respect to establishment and maintenance of a usability engineering process addressing user interactions with the device	IEC 60601-1-6: 2010, AMD1: 2013: Medical Electrical Equipment - Part 1-6: General Requirements for basic safety and essential performance – Collateral Standard: Usability

Testing/Evaluation Performed	Objective of Testing/Evaluation	Product Design Requirements Evaluated	Standards used for Testing/Evaluation (as applicable)
	including amended definitions. Excludes production and post-production monitoring and maintenance of the Usability Engineering Process.		
Module Comparison	Demonstrate that performance of device in comparison to the primary predicate device (K163326) is comparable	Software (EP, ASSR, DPOAE and TEOAE modules) Hardware (USB Jr. Duet platform, connected transducers, accessories and components used for each module)	N/A Bench testing performed using simulator, with evaluation of device output upon activation of each module. Evaluation of results performed alongside Bland-Altman analyses and correlation coefficient comparison. Results indicated that end-to-end performance of device system is comparable to predicate

Testing/Evaluation Performed	Objective of Testing/Evaluation	Product Design Requirements Evaluated	Standards used for Testing/Evaluation (as applicable)
			despite observed differences in performance

Other testing performed included the following:

- Software verification and validation for a Moderate Level of Concern (LOC), as recommended by the Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (effective 5/11/05)[1]

- Evaluation of cybersecurity risk management with implementation of modifications to procedures and labeling, as recommended by the Guidance Content of Premarket Submissions for Management of Cybersecurity in Medical Devices (effective 10/2/2014)[2]

- Mechanical Requirements Evaluation to demonstrate that functional mechanical product design requirements are satisfied

Clinical testing was not performed.

VIII. Conclusion

Based on the non-clinical performance data, the GSI Audera Pro™ is found to have a safety and effectiveness profile that is comparable to the predicate device.

[1] https://www.fda.gov/media/73065/download
[2] https://www.fda.gov/media/86174/download