May 11, 2018

Grason-Stadler, Inc.
Amy Yanta
Director of Regulatory Affairs
10395 West 70th Street
Eden Prairie, MN 55344

Re: K180287
Trade/Device Name: GSI Corti
Regulation Number: 21 CFR 874.1050
Regulation Name: Audiometer
Regulatory Class: Class II
Product Code: EWO
Dated: February 1, 2018
Received: February 1, 2018

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180287

Device Name
GSI Corti

Indications for Use *(Describe)*

The GSI Corti series is indicated for testing of cochlear function in infants, children and adults by measuring otoacoustic emissions (OAEs). The OAEs are generated by a series of clicks that are directed into the ear canal. Otoacoustic emissions are low level audio-frequency sounds that are produced by the cochlea as part of the normal-hearing process. Available evidence suggests that otoacoustic emissions are generated by the cochlea's outer hair cells and that the presence of OAEs is an indication that the outer hair cells are viable. Clinical evidence indicates that these emissions normally occur with normal hearing, or at most, mild hearing loss (usually 30-40 dB HL). The majority of hearing-impaired individuals will be identified by a simple OAE test.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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 as required by 21 CFR 807.92.

Administrative Information

Submitter: Grason-Stadler Inc.
10395 West 70th Street
Eden Prairie, MN 55344
Tel: 952-947-6097
Fax: 952-278-4401

Contact Person: Amy Yanta
Director of Regulatory Affairs
10393 West 70th Street
Eden Prairie, MN 55344
952-947-6097
amyy@diagnostic-group.us

Date Summary Prepared: January 29, 2018

Device Identification

Trade Name: GSI Corti
Common Name: audiometer, otoacoustic emission device
Device Classification Name: Audiometer
Device classification: Class II
Panel: Ear Nose & Throat
Classification Regulation: 874.1050
Product Code: EWO
Predicate Device 1: ER36 Series OAE Test System, cleared on 03/26/2015 via K150491

Device Description

Corti test system provides rapid measurement and documentation of Distortion Product Otoacoustic Emissions (DPOAEs) or Transient Evoked Otoacoustic Emissions (TEOAEs) at several frequencies.

The system consists of the instrument, probe, printer, single-use eartips replaceable probe tubes and other accessories. The Corti instrument contains the hardware and software for generating the test stimuli, measuring and displaying the OAEs, and storing the results until they are printed. The plastic housing contains circuit boards that provide the signal processing and display the test results. The instrument also contains a rechargeable lithium-ion battery to power the device. The instrument uses a liquid-crystal display (LCD) and three light-emitting diodes (LEDs) to provide a visual display of test status to the operator. Four push buttons located on the keypad of the device allow the user to control testing and printing, and to reset test protocols.

The Probe houses the speaker and microphone which produce test stimuli and measure the sound pressure level (SPL) present in the sealed ear canal. Interface of the instrument to the ear canal is

accomplished through disposable eartips, which fit onto the probe tube. The disposable eartips are color coded to facilitate easy selection by size.

Distortion Product Otoacoustic Emissions (DPOAEs) are acoustic signals that can be detected in the ear canal of a person with normal outer hair cell function, subsequent to stimulation of the auditory system with a pair of pure tones at frequencies f1 and f2. The resulting emission of interest is the distortion product tone at the frequency 2f1-f2.

The Corti instrument generates a series of test tones, directs them into the ear canal, and then measures the level of the DPOAE tone generated by the cochlea. By using different test frequencies, the Corti device provides an estimate of outer hair cell function over a wide range of frequencies.

Transient Evoked Otoacoustic Emissions (TEOAEs) are acoustic signals that can be detected in the ear canal of a person with normal outer hair cell function, subsequent to stimulation of the auditory system with a series of wideband clicks.

The Corti instrument generates a series of clicks, directs them into the ear canal, and then analyzes the spectrum of the returning signal, separating the noise and emission. By using band pass filters, the Corti device provides an estimate of outer hair cell function over a wide range of frequencies

Device Intended Use

The GSI Corti is a test instrument that measures otoacoustic emissions in infants, children, and adults.

The GSI Corti series is indicated for testing of cochlear function in infants, children and adults by measuring otoacoustic emissions (OAEs). The OAEs are generated by a series of clicks that are directed into the ear canal.

Otoacoustic emissions are low level audio-frequency sounds that are produced by the cochlea as part of the normal-hearing process. Available evidence suggests that otoacoustic emissions are generated by the cochlea's outer hair cells and that the presence of OAEs is an indication that the outer hair cells are viable. Clinical evidence indicates that these emissions normally occur with normal hearing, or at most, mild hearing loss (usually 30-40 dB HL). The majority of hearing-impaired individuals will be identified by a simple OAE test.

Technological Characteristics

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

Equivalence Predicate Chart 1:

Description	ER36 Series OAE Test System (K150491)	GSI Corti	Equivalency
Type	Audiometer	Audiometer	same
Regulation Number	21 CFR 874.1050 (otoacoustic emission device)	21 CFR 874.1050 (otoacoustic emission device)	same

Classification Product Code	EWO	EWO	same
Regulatory Class	Class II	Class II	same
Indications for Use	The ER36 is a test instrument that measures otoacoustic emissions in infants, children, and adults. The ER36 series is indicated for testing of cochlear function in infants, children and adults by measuring otoacoustic emissions (OAEs). The OAEs are generated by a series of clicks that are directed into the ear canal. Otoacoustic emissions are low level audio frequency sounds that are produced by the cochlea as part of the normal-hearing process. Available evidence suggests that otoacoustic emissions are generated by the cochlea's outer hair cells and that the presence of OAEs is an indication that the outer hair cells are viable. Clinical evidence indicates that these emissions normally occur with normal hearing, or at most, mild hearing loss (usually 30-40 dB HL). The majority of hearing-impaired individuals will be identified by a simple OAE test.	The GSI Corti is a test instrument that measures otoacoustic emissions in infants, children, and adults. The GSI Corti series is indicated for testing of cochlear function in infants, children and adults by measuring otoacoustic emissions (OAEs). The OAEs are generated by a series of clicks that are directed into the ear canal. Otoacoustic emissions are low level audio frequency sounds that are produced by the cochlea as part of the normal-hearing process. Available evidence suggests that otoacoustic emissions are generated by the cochlea's outer hair cells and that the presence of OAEs is an indication that the outer hair cells are viable. Clinical evidence indicates that these emissions normally occur with normal hearing, or at most, mild hearing loss (usually 30-40 dB HL). The majority of hearing-impaired individuals will be identified by a simple OAE test.	same
Target Population	Infants, children, and adults	Infants, children, and adults	same
OAE Specifications			
OAE Measurement Type	Distortion-Product OAE Transient-Evoked OAE	Distortion-Product OAE Transient-Evoked OAE	same
DPOAE Frequency Range	1.0 kHz to 12kHz	1.0 kHz to 12kHz	same
DPOAE Stimulus Level	40 to 65 dB SPL	40 to 65 dB SPL	same

DPOAE Automatic Pass/Fail Test	Yes	Yes	same
DPOAE Calibration	In-Ear self-calibration	In-Ear self-calibration	same
DPOAE f1/f2 Frequency Ratio	1.22	1.22	same
DPOAE Analysis Bands	4 to 6 bands available	4 to 6 bands available	same
TEOAE Frequency Range	500 Hz to 4000 Hz	500 Hz to 4000 Hz	same
TEOAE Stimulus Level	Adjustable, 70 to 85 dB SPL	Adjustable, 70 to 85 dB SPL	same
TEOAE Automatic Pass/Fail Test	Yes	Yes	same
TEOAE Calibration	In-Ear self-calibration	In-Ear self-calibration	same
TEOAE Analysis Bands	6	6	same
Instrument Characteristics and Specifications			
Instrument Type	Handheld	Handheld	same
Hand held Housing Shape	2.5in x 6in	7 in. x 2.75 in x 1.25 in	Larger device for better handle by user
Handheld Housing Material	PC-ABS	PC+ABS CX7240	Same (material name more specific)
Housing of Ear Probe	Machined Aluminum	Machined Aluminum	same
User Controls	4 button directional keyboard	4 button directional keyboard	same
4 Button Navigation Switch	Surface mount tactile switches	Surface mount tactile switches	same
Cable-Probe Connector	Proprietary durable polarized connector	Proprietary durable polarized connector	same
Test Records Stored in Internal Memory	Up to 250 tests	Up to 250 tests	same
Memory Type	Flash EEPROM	Flash EEPROM	same
Power Supply	Rechargeable Lithium-Ion Battery. Not accessible by user.	Rechargeable Lithium-Ion Battery. Not accessible by user.	same
Maximum Output	90 dB SPL	90 dB SPL	same

Test Probe Types	Cabled probe	Cabled probe	same
User Indicators	Monochrome or Color Character-based LCD display; 4 LED indicators	OLED Display	Provides a sharper image for user
Connection to Computer	USB interface	USB A to micro-B interface	Same (More specific description of USB)
Printer	Bluetooth wireless connection to AC or battery-powered thermal printer	Bluetooth wireless connection to AC or battery-powered thermal printer	same
Test Performance	AAMIANSIS3.6:2010 Specifications for Audiometers IEC 60645-1:2012: Electroacoustics - Audiometric Equipment - Part 1: Pure-Tone Audiometers IEC 60645-3:2007: Electroacoustics - Audiometric Equipment - Part 3: Test Signals of Short Duration, Second Edition IEC 60645-6:2009: Electroacoustics - Audiometric Equipment - Part 6: Instruments for the Measurement of Otoacoustic Emissions, First Edition 2009-04	AAMIANSIS3.6:2010 IEC 60645-1:2012 IEC 60645-3:2007 IEC 60645-6:2009	same
Operational and Safety	AAMIANSI 60601-1:2005(R): 2012: Medical Electrical Equipment, Part 1:General Requirements for Safety, Third Edition AAM IANSI IEC 62366:2007:(R)2013:Medical Devices - Application of Usability Engineering to Medical Devices, Second Edition 2007-03-01 ISO 14971:2007:Medical Devices, Application of Risk Management to Medical Devices, Second Edition 2007-03-01	IEC 60601-1:2005+A1:2012(E) ANSI/AAMI 60601-1:2005/(R) 2012 AAMI/ANSI/IEC 62366:2015 ISO 14971:2007 UL Registered, File E486032	Same

	UL Registered, File E359876		

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 "moderate" level of concern since a failure in the device may result in unacceptable loud stimuli which might affect the hearing of the patient. Additionally, a malfunction in the device may delay the proper diagnostic of the hearing problem in patients. The detailed information about the validation and verification of PASS/REFER for the OAE is provided in the GSI Corti Manual, e.g., PASS/REFER Criteria, Sensitivity and Specificity etc. Based on the fulfillment of the international standards for OAE, 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

The clinical validation was performed to determine substantial equivalence in the performance of the brand name GSI Corti to the ERO-SCAN. These instruments were used to perform Distortion-Product Otoacoustic Emissions (DPOAE) and Transient-Evoked Otoacoustic Emissions (TEOAE). The individual test results were evaluated for overall test result and signal-to-noise ratio at each frequency. The entire data set was evaluated for emission level, signal-to-noise ratio, as well as the noise floor. The diagnostic performance of the device was evaluated on a selection of test subjects. A population of approximately 80% normal hearing was targeted for the study population, with the remaining approximately 20% having a range of impairment from complete impairment (cavity) to mild hearing impairment. For each subject, the following tests were performed. These tests were performed in an alternating sequence, as arbitrarily determined by the clinical investigator. Each set of tests were performed in their entirety at each of the scheduled test times, on each of the two days.

DPOAE: 4 Frequency (2.0 kHz to 5.0 kHz(default DP screening protocol)) – 65/55 dB SPL Primaries – 4 Second Averaging Time
DPOAE: 6 Frequency (1.5 kHz to 6 kHz(default DP diagnostic protocol)) – 65/55 dB SPL Primaries – 4 Second Averaging Time
TEOAE: 6 Frequency (700 Hz to 4 kHz (default diagnostic TE protocol)) – 83 dB SPL Click Stimulus – 64 Second Maximum Time
TEOAE: 6 Frequency (1.5 kHz to 4 kHz (default TE screening protocol)) – 83 dB SPL Click Stimulus – 64 Second Maximum Time

The results were analyzed to determine if the device provided equivalent diagnostic results on the subject ears as another equivalent device. The results of the validation are considered evidence, when

combined with the verification testing, of the ability of the device to meet the requirements associated with the indications for use.

Based on the data and rationales in the clinical validation report it is concluded that for the indication for diagnose and evaluation of hearing;

- The devices demonstrates conformity with the essential principles
- Performance and safety claims have been met and documented
- All risks regarding indications for use and clinical data have been identified, addressed and evaluated
- Risks associated with the use of the devices are acceptable and weighted

Conclusion

We have compared the intended use and performance characteristics with the predicate device. The Corti was tested according to current standards and the differences found between the devices were related to minor differences of functionality, not in relation to safety and efficiency. The differences found between the devices were related to minor differences of functionality such as the Corti has a different splash screen on the device and user has option to recharge the batteries utilizing the device cradle in addition to using the charging cable. The Corti conforms to the current standards. After analyzing bench testing, safety, EMC, and software validation (with risk analysis) testing we conclude that the Corti is found to be substantially equivalent to the predicate device in technological characteristics and indications for use.