October 20, 2017

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

Re: K172403
Trade/Device Name: GSI Novus
Regulation Number: 21 CFR 874.1050
Regulation Name: Audiometer
Regulatory Class: Class II
Product Code: EWO, GWJ
Dated: August 9, 2017
Received: August 9, 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.

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 (DICE) 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 (DICE) 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,

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)*
K172403

Device Name
GSI Novus

Indications for Use *(Describe)*
The GSI Novus is intended to be used for the measurement and automated analysis of auditory evoked responses (auditory brainstem responses, ABR) and/or otoacoustic emissions (distortion product, DPOAE and transient evoked, TEOAE). These measures are useful in the screening evaluation, identification, documentation and diagnosis of auditory and hearing related disorders. The auditory evoked response (ABR) measurement is intended for newborns and infants up to 6 months of age. The otoacoustic emissions (DPOAE and/or TEOAE) measurement is intended for use in patients of all ages.

The GSI Novus is intended to be used by a healthcare professional such as an ENT doctor, nurse or audiologist or by a trained technician under the supervision of a professional. The device is intended to be used in a hospital, clinic, or other facility with a suitable quiet testing environment.

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.

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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."*

**Section 5: 510(k) Summary as required by 21 CFR 807.92.**

## Administrative Information

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Date Summary Prepared: August 7, 2017

## Device Identification

Trade Name: Novus
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 1: Titan (with DPOAE440 and ABRIS440), cleared on 05/05/2011 via K103760
Predicate Device 2: Titan (with TEOAE440), cleared on 06/20/2013 via K130795

## Device Description

The device is audiometric equipment used for testing of inner ear and auditory brainstem abnormalities.

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

Novus uses auditory brainstem response (ABR) 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.

The EEG is processed and analyzed automatically using the Novus'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.

Auditory brainstem response (ABR) 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.

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 GSI Novus is intended to be used for the measurement and automated analysis of auditory evoked responses (auditory brainstem responses, ABR) and/or otoacoustic emissions (distortion product, DPOAE and transient evoked, TEOAE). These measures are useful in the screening evaluation, identification, documentation and diagnosis of auditory and hearing related disorders.

The auditory evoked response (ABR) measurement is intended for newborns and infants up to 6 months of age. The otoacoustic emissions (DPOAE and/or TEOAE) measurement is intended for use in patients of all ages.

The GSI Novus is intended to be used by a healthcare professional such as an ENT doctor, nurse or audiologist or by a trained technician under the supervision of a professional. The device is intended to be used in a hospital, clinic, or other facility with a suitable quiet testing environment.

## Technological Characteristics

The Novus 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 | Titan with TEOAE440 (k130795) | Novus |
|---|---|---|
| Type | Audiometer | Audiometer |
| Regulation Number | 21 CFR 874.1050<br>(otoacoustic emission device) | 21 CFR 874.1050<br>(otoacoustic emission device) |
| Classification Product Code | EWO | EWO |
| Regulatory Class | Class II | Class II |
| Indications for Use | The Titan with TEOAE440 is intended for use in the audiologic evaluation and documentation of ear disorders | The GSI Novus is intended to be used for the measurement and automated analysis of |

| | | |
|---|---|---|
| | using Transient Evoked Otoacoustic Emissions.<br>The target population for Titan with TEOAE440 includes all ages. | auditory evoked responses (auditory brainstem responses, ABR) and/or otoacoustic emissions (distortion product, DPOAE and transient evoked, TEOAE). These measures are useful in the screening evaluation, identification, documentation and diagnosis of auditory and hearing related disorders.<br>The auditory evoked response (ABR) measurement is intended for newborns and infants up to 6 months of age.<br>The otoacoustic emissions (DPOAE and/or TEOAE) measurement is intended for use in patients of all ages.<br>The GSI Novus is intended to be used by a healthcare professional such as an ENT doctor, nurse or audiologist or by a trained technician under the supervision of a professional. The device is intended to be used in a hospital, clinic, or other facility with a suitable quiet testing environment.<br><br>Intended use differs due to the device encompassing all functions into one device. |
| Target Population | The devices are suitable for all populations including new-born infants | The device are suitable for all populations including new-born infants |
| 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. | To be used by trained personnel only such as audiologists, ENT surgeons, doctors, hearing healthcare professionals or personnel with similar level of education. (or trained user with supervision of a professional) |
| TEOAE Stimulus | | |
| Frequency Range | 500 to 5500Hz | 500 to 5500Hz |

| | | |
|---|---|---|
| Stimuli Type | Non-Linear and Linear<br>Short duration signal (Click)<br>According to IEC 60645-3 | Non-Linear and Linear<br>Short duration signal (Click)<br>According to IEC 60645-3 |
| 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 |

Equivalence Predicate Chart 2:

| | Titan (K103760) | | Novus | |
|---|---|---|---|---|
| Description | With ABRIS440 | With DPOAE440 | With ABRIS | With DPOAE |
| Type | Auditory Brainstem Response – Audiometric equipment | Audiometer | Auditory Brainstem Response – Audiometric equipment | Audiometer |
| Regulation Number | 21 CFR 882.1900 (Evoked response auditory stimulator) | 21 CFR 874.1050 (otoacoustic emission device) | 21 CFR 882.1900 (Evoked response auditory stimulator) | 21 CFR 874.1050 (otoacoustic emission device) |
| Classification Product Code | GWJ | EWO | GWJ | EWO |
| Regulatory Class | Class II | Class II | Class II | Class II |
| Indications for Use | The Titan with ABRIS440 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 Titan with DPOAE440 is intended for use in the audiologic evaluation and documentation of ear disorders using Distortion Product Otoacoustic Emissions. | The GSI Novus is intended to be used for the measurement and automated analysis of auditory evoked responses (auditory brainstem responses, ABR) and/or otoacoustic emissions (distortion product, DPOAE and transient evoked, TEOAE). These measures are useful in the screening evaluation, identification, documentation and diagnosis of auditory | The GSI Novus is intended to be used for the measurement and automated analysis of auditory evoked responses (auditory brainstem responses, ABR) and/or otoacoustic emissions (distortion product, DPOAE and transient evoked, TEOAE). These measures are useful in the screening evaluation, identification, documentation and diagnosis of auditory |

| | | | | |
|---|---|---|---|---|
| | | | and hearing related disorders.<br>The auditory evoked response (ABR) measurement is intended for newborns and infants up to 6 months of age. The otoacoustic emissions (DPOAE and/or TEOAE) measurement is intended for use in patients of all ages.<br>The GSI Novus is intended to be used by a healthcare professional such as an ENT doctor, nurse or audiologist or by a trained technician under the supervision of a professional. The device is intended to be used in a hospital, clinic, or other facility with a suitable quiet testing environment.<br><br>Intended use differs due to the device encompassing all functions into one device. | and hearing related disorders.<br>The auditory evoked response (ABR) measurement is intended for newborns and infants up to 6 months of age. The otoacoustic emissions (DPOAE and/or TEOAE) measurement is intended for use in patients of all ages.<br>The GSI Novus is intended to be used by a healthcare professional such as an ENT doctor, nurse or audiologist or by a trained technician under the supervision of a professional. The device is intended to be used in a hospital, clinic, or other facility with a suitable quiet testing environment.<br><br>Intended use differs due to the device encompassing all functions into one device. |
| Target Population | Children and newborn | The patient group includes all ages and sexes. | Children and newborn | The patient group includes all ages and sexes. |
| Anatomical Sites | Examination of Ear and hearing nerves | Examination of Ear | Examination of Ear and hearing nerves | Examination of Ear |
| Safety Standards | IEC 60601-1 | IEC 60601-1 | IEC 60601-1 | IEC 60601-1 |
| Performance standard | IEC 60645-7 | IEC 60645-6 | IEC 60645-7 | IEC 60645-6 |
| Device Type | Screening device (PASS/REFER) result | Screening and diagnostic | Screening and diagnostic device (PASS/REFER) result | Screening and diagnostic device (PASS/REFER) result |
| System Configuration | 1 -channel ABR system operated through a handheld base unit. The base unit can be operated stand | [redacted] | 1 -channel ABR system operated through a handheld base unit. The | [redacted] |

| | | | | |
|---|---|---|---|---|
| | alone or PC controlled through USB or Bluetooth. | | base unit can be operated as stand-alone device.<br><br>This allows the freedom of flexibility. The data can be transferred to the PC via USB port for secure transmission. | |
| Display Information | PASS/REFER status, indicated with value between 0 and 100% where 100% indicates a pass. EEG peak or RMS value, rejection status, residual noise and what transducer(s) are detected. | | Noise status, detected transducer, artifact %, PASS/REFER status.<br><br>This creates simplicity for user use. | |
| Stimulus | Click and Chirps | 2 pure tones | Click and Chirps | 2 pure tones |
| Electrode quality check | YES | | YES | |
| Impedance Test | Before recording: Electrode impedance is measured if they are above 10kOhm, below 10 kOhm or below 3 kOhm. | | Similar impedance test; acceptable impedance <40kOhm.<br><br>Below <40kOhm is acceptable value and one test value provides quicker values to reference. | |
| Binaural screening | YES | | YES | |
| Pre-amplifier channels | 1 | | 1 | |
| Stimulus rate | 90/s | | 90/s | |
| Pre-amplifier Gain | 64 dB (fixed) + 64dB (Variable) | | 64 dB (fixed) + 64dB (Variable) | |
| Stimulus Level | 30,40 and 45dB HL | 30 dB SPL to 80 dB SPL | 30,40 and 45dB HL | 30 dB SPL to 80 dB SPL |
| Masking | None | | None | |
| Transducers | Titan Probe (mono) Stereo headset: TDH39 and EAR3A | | OAE probe, RadioEar IP30 insert earphone<br><br>Titan used different accessories but Novus accessories perform same functions. | |
| | | | | 500Hz – 10kHz |

## 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 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. The detailed information about the validation and verification of PASS/REFER algorithms for the OAE and ABR modules is provided in the GSI Novus Manual, e.g., PASS/REFER Criteria, Sensitivity and Specificity etc. 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 devices. The Novus 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 Novus conforms to the current standards. After analyzing bench testing, safety, EMC, and software validation (with risk analysis) testing we conclude that the Novus is found to be substantially equivalent to the predicate devices in technological characteristics and indications for use.