

5974237

"510(k) SUMMARY"
Summary of Safety and Effectiveness

Submitter's Name & Address: Grason-Stadler Inc.
1 Westchester Drive
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FEB 10 1998

Contact Person & Telephone: Norman L. Schultz
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Date Summary Prepared: September 12, 1997

Device Name: Classification Name - Audiometer
Common/Usual Name - Screening Audiometer
Proprietary Name - GSI 70 AudioPath™ Screener

Predicate Device: Grason-Stadler Inc. model GSI 60 DPOAE system (ref. 510(k) #K934658S1) GSI 37 Auto Tympanometry (ref. 510(k) #K911095), and the GSI 17 Screening Audiometer (ref. 510(k) #K902540)..

Device Description, Intended Use & Effectiveness:

The Grason-Stadler Inc. model GSI 70 AudioPath™ Screener is similar to and predicated upon the Grason-Stadler Inc. model GSI 60 Otoacoustic Emissions/Screening Audiometer, the GSI 37 Auto Tympanometry Middle Ear Analyzer, and the GSI 17 Pure Tone Screening Audiometer. The purpose of this device is to detect as well as track hearing loss and abnormal middle ear conditions in all ages of patients (From premature infants through adults age). The instrument has a battery of testing capabilities such as Otoacoustic Emission Screening, Tympanometry, and Pure Tone Audiometry. The device is intended to be used by trained personnel in a medical or school environment. This device is not intended for use in prescribing or fitting assistive listening devices such as hearing aids, cochlea implants or wireless microphones.

Technological Characteristics:

See attachment "A" for a comparison of the GSI 70 AudioPath™ Screener to the predicate device.

Safety:

The GSI 70 AudioPath™ Screener is designed to provide electrical safety to the patient as well as the user. The system is designed to meet the following standards related to electrical safety: IEC 601-1, UL2601, and CSA 601-1-M90. To prevent excessive tone levels within the ear the system is designed with watchdog timers that monitor the system and disable the tone generation when disparity is detected. Also, the speakers that are used within the probes are

incapable of producing enough decibels to permanently damage the ear. The pump for the tympanometry function has been designed such that the volume of the pump is incapable of producing a pressure that would exceed the safe level as specified within ANSI S3.39.

The system will also be certified to the following standards:

EMI EN55011	Group 1 Class B requirements (medical equipment, conducted and radiated emissions).
IEC801-2	ESD Susceptibility.
IEC801-3	Radiated Electromagnetic Field Susceptibility.
IEC801-4	Conducted Susceptibility to Line Transients.
CE Mark	Conforms with provisions of European Council Directive 93/42/EEC concerning medical devices.

Summary of Effectiveness:

The GSI 70 AudioPath™ Screener is a consolidation of three current audiological products into one portable instrument making it equivalent or better in effectiveness for the detection and tracking of hearing loss and abnormal middle ear conditions in all ages of patients (from premature infants through adults).

Attachment A
Chart of Predicate Device Comparison

Technological Specification	GSI 17	GSI 37	GSI 60	GSI 70
Power Source	Powered by a low voltage DC wall mounted power supply.	Powered by a low voltage DC wall mounted power supply.	Powered by battery or a low voltage DC wall mounted power supply.	Powered by re-chargeable battery.
Battery Low Indication.	None	None	LED lights on front of instrument.	Battery low indicator on display.
Safety Compliance.	IEC 601-1 and UL544	IEC 601-1 and UL544	IEC 601-1 and UL2601-1	IEC 601-1 and UL2601-1
Computer Interface	RS232	None	DSP Board plugged into printer interface.	IRDA communications
Audiometry	Technology used is speaker headset that present tones to patient which if perceived is indicated by a patient response switch. Tone quality and frequency specified per ANSI S3.6.	N/A	N/A	Tones are presented by a miniature speaker within the probe which if perceived is indicated by the patient using a response switch. Tone quality and frequency specified per ANSI S3.6.
Tympanometry	N/A	Tones are presented during a pressurization of the ear by a miniature pump and response is recorded by a microphone. Tone quality and frequency controlled by ANSI S3.39.	N/A	Same as GSI 37
OAE Probe Design	N/A	N/A	Two speakers and a microphone present and record response from cochlea of ear.	Same as GSI 60
DSP Software for OAE Function			GSI 60 DSP Software	Same
Supporting software for OAE Function			Windows based software that graphs DP result, allows changes to protocol, export of data, and changes to patient ID.	Windows based software that shows result, allows export of data, and updating of patient ID.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 10 1998

Norman L. Schultz
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Re: K974237
GSI 70 AudioPath™ Hearing Screener
Dated: November 7, 1997
Received: November 12, 1997
Regulatory class: II
Procode: 77 EWO, 21 CFR 874.1050
77 ETY, 21 CFR 874.1090

Dear Mr. Schultz:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to 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). 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K974237

Device Name: GSI 70 AudioPath™ Hearing Screener

Indications For Use:

The Grason-Stadler Inc. model GSI 70 AudioPath™ Hearing Screener is similar to and predicated upon the Grason-Stadler Inc. model GSI 60 Otoacoustic Emissions/Screening Audiometer, the GSI 37 Auto Tym Middle Ear Analyzer, and the GSI 17 Pure Tone Screening Audiometer. The purpose of this device is to detect as well as track hearing loss and abnormal middle ear conditions in all ages of patients (from premature infants through adults). The instrument has combined a battery of testing capabilities such as Otoacoustic Emission Screening, Tympanometry, and Pure Tone Audiometry within one hand held instrument. The device is intended to be used by trained personnel within a medical or school environment. This device is not intended for use in prescribing or fitting assistive listening devices such as hearing aids, cochlear implants or wireless microphones, or to diagnose the causes of detected hearing losses.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)



Concurrence of CDRH, Office of Device Evaluation (ODE)

David L. Berger
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K974237

Prescription Use

OR

Over-The-Counter Use

(Optional Format 1-2-96)