JUN - 6 1997

K970324

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

Submitter's Name & Address: Grason-Stadler Inc.
1 Westchester Drive
Milford, N.H. 03055-3056

Contact Person & Telephone: Norman L. Schultz
(603) 672-7303

Date Summary Prepared: January 22, 1997

Device Name: Classification Name - Audiometer
Common/Usual Name - Otoacoustic Emissions/Screening Audiometer
Proprietary Name - GSI SA60 DPOAE System

Predicate Device: Grason-Stadler Inc. model GSI 60 DPOAE system (ref. 510(k) #K934658S1).

Device Description, intended Use & Effectiveness:

The Grason-Stadler Inc. model GSI SA60 Otoacoustic Emissions/Screening Audiometer is similar to and predicated upon the Grason-Stadler Inc. model GSI 60 Otoacoustic Emissions/Screening Audiometer. The GSI SA60 is to be used as part of an audiometric test battery. The purpose of this device is to assess the status of cochlear function by presenting an acoustic stimulus (i.e. the primary tone pair) to evoke an otoacoustic emission (i.e. the distortion product) which is measured. The GSI 60 and the GSI SA60 utilize a probe containing a microphone and two (2) independent speakers (one for each primary tone) to present the acoustic stimulus and measure for the presence of an evoked otoacoustic emission.

Technological Characteristics:

See attachment "A" for a comparison of the GSI SA60 to the predicate device.

Safety:

The GSI SA60 system is designed to provide electrical safety to the patient as well as the user. The system is designed to be used with a notebook computer powered either by its internal battery or by the supplied low voltage ungrounded DC power supply. The notebook computer used with

the system will be specified to meet standards pertaining to the safety of Information Technology Equipment namely: IEC 950, UL1950, CSA 950 and CE mark. The instrument portion of the system may be powered by its internal battery or by the supplied low voltage DC power supply. The instrument enclosure is also connected to protective earth (ground) when powered by the low voltage DC power supply. No other mains powered equipment will be connected to the system during patient testing. The front panel of the instrument will have status indicators that inform the user of the following conditions: 1) Battery charging, 2) low battery voltage, and 3) power applied. The battery charger status will be constantly monitored and the instrument will not collect data when the battery charge is too low to reliably operate the instrument. The system is designed to meet the following standards related to electrical safety: IEC 601-1, UL2601, and CSA 601-1-M90. A preliminary design review was conducted with a competent test laboratory and the design will meet requirements for electrical safety of an IEC 601-1 class 1, type B medical instrument.

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 89/336/EEC Electromagnetic Compatibility Directive.

Summary of Effectiveness:

The GSI SA60 is an extension of the current GSI 60 system and operates in the same manner. The GSI SA60 allows the use of the system with a notebook computer without the need for a docking station which is required for the GSI 60 (See attachment "A" Chart of Predicate Device Comparison). The GSI SA60 is therefor more portable than the GSI 60 making it equivalent or better in effectiveness for the testing of cochlear function.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 6 1997

Norman L. Schultz
Senior Quality Engineer
Grason-Stadler, Inc.
1 Westchester Drive
Milford, NH 03055-3056

Re: K970324
Grason-Stadler GSI SA60 DPOAE Otoacoustic Emission (OAE) Test Instrument
Dated: March 18, 1997
Received: March 19, 1997
Regulatory class: II
21 CFR 874.1050/Procode: 77 ETW

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 (for the indications for use stated in the enclosure) 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4591 for Radiology devices, or 594-4613 for Ear, Nose and Throat devices. 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

Enclosure

510(k) Number (if known): K970324

Device Name: GSI SA60 DPOAE System

Indications For Use:

The Grason-Stadler Inc. model GSI SA60 Otoacoustic Emissions/Screening Audiometer is similar to and predicated upon the Grason-Stadler Inc. model GSI 60 Otoacoustic Emissions/Screening Audiometer. The GSI SA60 is to be used as part of an audiometric test battery. The purpose of this device is to assess the status of cochlear function by presenting an acoustic stimulus (i.e. the primary tone pair) to evoke an otoacoustic emission (i.e. the distortion product) which is measured. The GSI 60 and the GSI SA60 utilize a probe containing a microphone and two (2) independent speakers (one for each primary tone) to present the acoustic stimulus and measure for the presence of an evoked otoacoustic emission.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K970324

Prescription Use ✓ OR Over-The-Counter Use ___

(Optional Format 1-2-96)