K982642

OCT 21 1998

'510 (k) Summary'
Summary and safety effectiveness

Submitter's Name & Address: Fischer-Zoth
Audiologic Systems
11309 South Brandon Park Dr. 3
Sandy, Utah, 84092

Contact person & Telephone: Mr. Michael Soerensen
(801) 253 0704

Data summary prepared: May 5, 1998

Device name: Classification Name - Audiometer
Common/Usual Name - Screening Audiometer
Proprietary name - Echo-Screen

Predicate Device: Grason Stadler Inc. model GSI70 AudioPath Screener (ref. 510(k) #K974237) and Otodynamics LTD. model ILO88 (ref. 510(k) #K962995,

Device description , intended Use & Effectiveness:
The Fischer-Zoth Audiologic System model 'Echo-Screen' is based upon Otoacoustic Emissions and it is similar to the Grason Stadler Inc. GSI70 AudioPath Screener and the Otodynamics OAE Analyser, model ILO88.

The purpose of the device is the reliable and earliest possible detection of hearing disorders due to cochlear dysfunction. It can be used beginning from neonates to adults.

The 'echo-screen' is a handheld, automated OAE-based screening-system which is easy to use. The measurement flow is menu guided and the evaluation is based upon signal statistics.
It is intended to be used by trained personnel in a medical or school environment.
The echo-screen is not intended for use in prescribing or fitting assisstive listening devices such as hearing aids or cochlea implants.

Technological Characterisitics: see also Attachment A
- Probe: miniature probe easy to apply even for premature infants
- Hardware:
  Hand held device : size 21,5x10x5,4cm , weight 600g.
  Battery powered : 6V/1000mAh, rechargeable
  Stimulus Rate: 40....100Hz
  Signal Bandwidth : 1,4KHz to 4KHz
- Software: echo-screen evaluation SW
  Automated stimulus adjustment and online control
  Signal statistical criterion for 'PASS' condition
  Additional hints to measurement quality (stimulus stability and artefact rate)

Safety:
  Battery powered, no connection to mains required
  Sound Pressure level: 70-85 dB SPL maximum

Safety:

The 'Echo-Screen' Screening System is designed to provide electrical safety to the patient as well as the user. The system is designed to meet the following standards related electrical safety: IEC601-1, UL2601 and VDE750 (German MedGv).

The echo-screen is a stand alone-system. It is battery powered with a 6V battery. During operation there are no connections to the mains. There are no conductive connections to the patient or to the user during measurement.

To prevent excessive tone levels within the ear, the echo-screen system continiously controls the level of the output tone or click-burst. The max. output level is controlled via Software to 85dB SPL (sound pressure level) and the electronic hardware is build in such a way, that the speakers within the probe are incapable of producing enough decibels to permanently damage the ear.

The system will also be certified according to the following standards:

- ISO 9001 (EN29001)	Quality Management System
- EN46001	Class I or Class IIa device
- EN 55011	Group 1 (medical equipment, conducted and radiated emissions)
- IEC801-3	Radiated Electromagnetic Field Susceptibility
- CE Mark	Conforms the provisions of Eruopean council Directive 93/42EEC concerning medical devices.

Summary of Effectiveness:

The 'echo-screen' is a portable OAE based screening system.
Its aim is to detect and track hearing loss and abnormal cochlear conditions as early as possible in the child's life. The automated test makes it easy to use by trained personnel in a medical or clinical environment.

Attachement A

Technological Specification	**GSI70**	**echo-screen**
Power source	Powered by rechargeable battery	Powered by rechargeable battery
Battery Low Indication	Battery low indicator	Battery low indicator
Safety Compliance	IEC 601-1 and UL2601-1	IEC601-1 and UL2601-1
Computer interface	IRDA communication	none, during measurement
Audiometry	Tones are presented to a miniature speaker within the probe which perceived is indicated by the patient using a response switch. Tone quality and frequency specified per ANSIS3.6	Tones (clicks) are presented to a miniature speaker within the probe and controlled via SW. The response from the cochlea is received and registrated. Click tone quality and amplitude is controlled via SW and HW and is limited to a max. output level 85dB SPL.
OAE probe design	Two speakers and a microphone present and record response from cochlea of ear.	One speaker and a microphone present and record response from cochlea of ear.
SW	GSI 60 SW	Echo-screen Automated Evaluation SW
Supporting SW	Windows based SW that shows result., allows export of data, and updating of patient ID	C-based SW, that shows evaluation results, artefact rate, stimulus stability. After measurement export of test-result and patient data are possible

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 21 1998

David G. Wood, Esq.
Fischer-Zoth
Audiologic System, Inc.
11309 Brandon Park Drive
Sandy, Utah 84092

Re: K982642
Echo-Screen
Dated: July 27, 1998
Received: July 29, 1998
Regulatory class: II
21 CFR 874.1050/Procode: 77 EWO

Dear Mr. Wood:

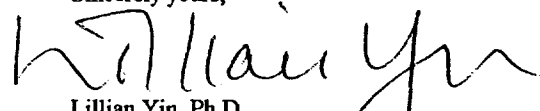
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 Current Good Manufacturing Practice requirements, 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/dsma/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): K982642

Device Name: ECHO-SCREEN

Indications For Use:

The Echo-Screen Otoacoustic Emissions Test Instrument is a hand-held instrument with an attached probe (that is placed in the outer ear canal) which emits sound that evokes otoacoustic emissions. A microphone in the probe picks up the emissions if any are present, and the device then analyzes the emissions and mathematically separates noise from cochlear emissions. The presence of these emissions indicates cochlear function in adults, infants and children. The instrument requires no active participation from the patient.

Otoacoustic emissions (OAEs) are low-level audio-frequency sounds that are generated by the outer hair cells of the cochlea in response to sound input. The presence of OAEs is an indication of cochlear function. If the Echo-Screen signals a "pass" reading as it analyzes the presence of OAEs, the clinician can determine that the cochlea is operating normally.

(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 K982642

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)