JUN 1 4 2002

K013977

'510 (k) Summary'
Summary and safety effectiveness

Submitter's Name & Address: Fischer-Zoth
Audiologic Systems
1257 W. Margaret View Circle
Riverton, UT 84065

Contact person & Telephone: Mr. Michael Sorensen
(801) 541 1123

Data summary prepared: November 8th, 2001

Device name: Classification Name – Audiometer, Neurology
Common/Usual Name - Screening Audiometer
Proprietary name – Echo-Screen T, TA, TD, TDA, TC

Predicate Devices:
Fischer-Zoth, model Echo-Screen: 510(k) K982642
SLE Limited, model SABRE: 510(k) K993177
see also: Appendix A

Device description , intended Use & Effectiveness:
The Fischer-Zoth Audiologic Systems model family 'Echo-Screen T' consisting of Echo-screen T, Echo-Screen TA, Echo-Screen TD, Echo-Screen TDA, Echo-Screen TC are based upon Otoacoustic Emissions (OAE) and Auditory Brainstem Response (ABR) technology. Similar techniques and methods are – among others - used by the Fischer-Zoth model Echo-Screen and SLE Limited model SABRE.

The device is intended to screen hearing for newborns through adults, including geriatric patients. The device does not measure hearing per se, but helps to determine whether or not a hearing loss may be present.

The 'Echo-Screen T' product family are handheld, automated OAE- and ABR based hearing screening systems which are easy to be used. The measurement flow is menu guided and the evaluation is based upon signal statistics. They are intended to be used by trained personnel in a medical or school environment. The Echo-Screen T models are not intended for fitting assistive listening devices such as hearing aids or cochlea implants.

Technological Characterisitics: (also see Appendix B)
- Probe: miniature probe easy to apply even for premature infants
- Electrodes: GXY, from Medicotest Inc. 510(k) #k931430
  or other FDA-approved products
- Hardware:
  Hand held device : size 21,5x10x5,4cm , weight 600g.
  Battery powered : 6V/1500mAh, 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 is possible during measurement
Sound Pressure level: 70-85 dB SPL maximum
Current through electrodes limited to < 10µA 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 T models are stand alone-system. They are battery powered with a 6V battery. During operation there are no connections to the mains.
During measurement there is a conductive connection to the patient via three Electrodes. The current through each single channel during the measurement is actively limited to < 5µA.
To prevent excessive tone levels within the ear, the Echo-Screen T models are continuously controlling 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	Quality Management System
- EN 60601	Safety
- EN 46001	Class IIa device, disposable are Class I
- EN 55011	Group 1 (medical equipment, conducted and radiated emissions)
- IEC801-3	Radiated Electromagnetic Field Susceptibility
- CE Mark	Conforms the provisions of European council Directive 93/42EEC concerning medical devices.

Summary of Effectiveness:

The 'Echo-Screen T' models are portable OAE/ABR based screening systems.
The aim is to detect and track hearing loss and abnormal middle ear conditions as early as possible in the person's life. Due to the automated test it easy to be used by trained personal (nurses,..) in a medical or school environment.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 14 2002

Mr. Michael Sorensen
President
Fischer-Zoth Audiologic Systems, Inc.
1257 W. Margaret View Circle
Riverton, UT 84065-4017

Re: K013977
Trade/Device Name: Echo-Screen T, TA, TD, TDA, TC
Regulation Number: 882.1900
Regulation Name: Evoked response auditory stimulator
Regulatory Class: II
Product Code: GWJ
Dated: March 14, 2002
Received: March 19, 2002

Dear Mr. Sorensen:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 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); 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.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K013977

ECHO-SCREEN T, TA, TD, TDA, TC

INDICATIONS FOR USE:

The Fischer-Zoth Audiologic Systems model family "Echo-Screen T" consisting of Echo-screen T, Echo-Screen TA, Echo-Screen TD, Echo-Screen TDA and Echo-Screen TC are based upon Otoacoustic Emissions (OAE) and Auditory Brainstem Response (ABR) technology.

The device is intended to screen hearing for newborns through adults, including geriatric patients. The device does not measure hearing per se, but helps to determine whether or not a hearing loss may be present.

The "Echo-Screen T" product family consists of handheld, automated OAE and ABR based hearing screening systems which are easy to use. The measurement flow is menu guided and the evaluation is based upon signal statistics. The "Echo-Screen T" devices are intended to be used by trained personnel in a medical or school environment. The "Echo-Screen T" models are not intended for fitting assistive listening devices such as hearing aids or cochlear implants.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use__X__ OR Over-The Counter Use____
(per 21 CFR 801.109

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013977