AUG 1 1 2003

K031713

VIASYS Healthcare
NeuroCare Group

Summary of Safety and Effectiveness

Company Name: VIASYS Healthcare
NeuroCare Group
5225 Verona Road, Building 2
Madison, WI 53711

Contact: Glen Hermanson, Manager of Standards and Compliance
Phone: 608 441-2065
Fax: 608 441-2007

Summary Date: August 7, 2003

Trade Name: Audiometer, Otoacoustic Emission and Auditory Brainstem Response Comfort Cup and Ear Tip Accessories

Common Name: Audiometer, Evoked Response Auditory Stimulator Accessory

Classification Name: 21 CFR 874.1050, Audiometer, Class II (510(k) exempt), Product Code: EWO

21 CFR 882.1900, Evoked Response Auditory Stimulator, Class II, Product Code: GWJ.

Predicate Device:

510(k)	Manufacturer	Product Code	Class	Trade Name
K024205	Everest Biomedical Instruments Company Chesterfield, MO	EWO	II	Audioscreener OAE + ABR
K974237	Grason-Stadler Inc.	EWO	II	GSI 70 AudioPath Screener
K934658	Grason-Stadler Inc.	ETW	II	GSI 60 DPOAE System
K911095	Grason-Stadler Inc.	ETY	II II	GSI 37 Auto Tymp
K902540	Grason-Stadler Inc.	EWO	II	GSI 17 Screening Audiometer

1.0 Description of Device

The audiometer, otoacoustic emission (OAE) and auditory brainstem response (ABR) accessories addressed in this pre-market notification are Comfort Cup and Eartip.

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These devices are used to couple auditory stimulus into the ear or ear canal to support audiometer, OAE and ABR testing. Both devices connect to the audiometer, OAE and ABR devices through a sound conducting tube. The sound from the audiometer, OAE and ABR devices are conducted through the sound conducting tube to the ear in the application of the Comfort Cup or to the ear canal in the applications of the Eartip. The Comfort Cup and Eartip accessories are single patient use disposables.

2.0 Intended Use

The indication for use of the audiometer, OAE and ABR accessories are:
The Comfort Cup and Ear Tip accessories are for use with non-Grason Staler (GSI) Audiometer, Otoacoustic Emission and Auditory Brainstem Response devices and are patient applied parts to support auditory evaluation studies.

3.0 Technological

The Comfort Cup and Eartip accessories are passive devices to support coupling of auditory stimulus to the ear and ear canal.

4.0 Conclusions

The intended use and technology of the Comfort Cup and Eartip accessories as audiometer, otoacoustic emission and auditory brainstem response accessories is the same as the accessories reviewed in Everest Medical and Grason-Stadler premarket notifications. The only difference is the use of these accessories with non-Grason-Stadler devices. This change does not raise new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 11 2003

VIASYS HealthCare
NeuroCare Group
c/o Gary Syring, Principal Consultant
Quality & Regulatory Assocociates, LLC
800 Levanger Lane
Stoughton, WI 53589

Re: K031713
Trade/Device Name: Comfort Cup and Eartip Accessories, for use with Non-GSI Audiometer, Otoacoustic Emission and Auditory Brainstem Response Devices
Regulation Number: 21 CFR 874.1050; 21 CFR 882.1900
Regulation Name: Audiometer; Evoked response auditory stimulator
Regulatory Class: Class II (exempt); Class II
Product Code: EWO; GWI
Dated: May 29, 2003
Received: June 5, 2003

Dear Mr. Syring:

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), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K031713

Device Name: Audiometer, Otoacoustic Emission and Auditory Brainstem Response Comfort Cup and Ear Tip Accessories

Indications For Use:

The Comfort Cup and Ear Tip accessories are for use with non-Grason Stadler (GSI) Audiometer, Otoacoustic Emission and Auditory Brainstem Response devices and are patient applied parts to support auditory evaluation studies.

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

David R. Mayle
for ENT

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)