K061104

MAY 3 2006

510(k) Summary of Safety and Effectiveness

Submitter

Name and address:	GN Otometrics A/S
	Dybendalsvaenget 2
	DK-2630 Taastrup
	Denmark
Phone:	+45 7211 1555
Fax:	+45 7211 1548
Contact person:	Per Pape Thomsen

Summary prepared: February 15, 2006

Device name

Common/Usual name:	Audio Fitting System
Trade/Proprietary name:	SpeechLink 100 type 1053
Classification name:	Hearing aid calibrator and analysis system

Predicate devices

SpeechLink is similar to the product Audioscan Verifit Model VF-1 (K012306) but differs in three ways: body worn operation powered by battery, number of tests available and wireless computer interface.

Wireless computer interface and battery operation is currently performed by Otoflex 100 Type 1012 (K033645).

Description

The SpeechLink is a PC-based system that contains hardware and software for one or more applications. The applications are controlled from self-contained software modules installed on a common software platform. The following applications are available: Audio fitting system and Simulator system.

The fitting system consists of a neckset, a charger unit with mains adapter, two probes connected to the neckset, software for installation on a PC and hardware for connection to a PC. The neckset is connected to the PC via a Bluetooth radio link, i.e. no physical connection to the PC.

The simulator consists of software for installation on a PC and hardware for connection to a PC.

Indications for Use

The SpeechLink 100 is a hearing aid calibrator and analysis system that is an electronic reference device intended to calibrate and assess the electroacoustic frequency and sound intensity characteristics emanating from a hearing aid.

Technological Characteristics

Device Specifications	**SpeechLink 100**	**Audioscan Verifit**
Safety compliance	IEC 60601-1	IEC 60601-1
Construction type	Body worn main unit, PC based system	Desktop system
Power source	Battery	Mains
Computer interface	Bluetooth radio link	RS232 cable connection
Supporting software	NOAH database SW	NOAH database SW
ANSI real ear requirements	Meets ANSI S3.46 1997 real-ear system requirements where applicable	Meets ANSI S3.46 1997 real-ear system requirements
Frequency range	125 – 8,000 Hz generation and measurement	200 – 8,000 Hz generation and measurement
Stimulus types (levels, dB SPL)	Pink noise (40 – 90)	Pink noise (40 – 90)
	Digitized conversations male/female (55 – 75)	Digitized individual male speech (55 – 75)
	Digitized conversations female/male (55 – 75)	Digitized individual female speech (55 – 75)
	Digitized conversations male/female/child (55 – 75)	Digitized individual child speech (55 – 75)
	International Collegium of Rehabilitative Audiology (ICRA) speech (55 – 75)	International Collegium of Rehabilitative Audiology (ICRA) speech (55 – 75)

Performance testing

Speech mapping recordings were measured simultaneously using the GN Otometrics SpeechLink 100 and the Audioscan Verifit VF-1. The probe microphone tubes were carefully positioned to measure the frequency response in the exact same location in the sound field.

The results show that there is high agreement between the measurements from the systems and that any observable differences between the peak curves are smaller than the tolerances regulated by the standard IEC 61669 (2001-01) Electroacoustics - Equipment for the measurement of real-ear acoustical characteristics of hearing aids.

It is therefore concluded that the two systems are equally accurate.

Safety

SpeechLink is designed to provide safety to the patient as well as the user and complies with:

- EN 60601-1:1990, UL 60601-1:2003, CAN/CSA-C22.2 NO 601.1-90:1990 Medical Electrical Equipment. Part 1: General requirements for safety
- EN 60601-1-1:2001: Medical Electrical Equipment. Part 1: Generel requirements for safety. 1. Collateral standard: Safety requirements for medical electrical systems
- EN 60601-1-2:2001 Medical Electrical Equipment. Part 1-2: Generel requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests

SpeechLink is designed, developed and manufactured according to:

- ISO 9001:2000 Quality Management Systems – Requirements
- ISO13485:2003 Quality management systems - Requirements for regulatory purposes

Effectiveness

The SpeechLink is a hearing aid calibrator and analysis system for hearing instrument fitting using spectral analysis. SpeechLink is of a technology type that is available and accepted in the market

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 3 2006

GN OTOMETRICS A/S
c/o Mr. Daniel W. Lehtonen
Intertek Testing Services
2307 East Aurora Road
Unit B7
Twinsburg OH 44087

Re: K061104
Trade/Device Name: SpeechLink100 type 1053
Regulation Number: 21 CFR 874.3310
Regulation Name: Hearing aid calibrator and analysis system
Regulatory Class: Class II
Product Code: ETW
Dated: April 19, 2006
Received: April 21, 2006

Dear Mr. Lehtonen:

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) 827-8910. 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/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061104

Device Name: SpeechLink 100 type 1053

Indications For Use:

The SpeechLink 100 is a hearing aid calibrator and analysis system that is an electronic reference device intended to calibrate and assess the electroacoustic frequency and sound intensity characteristics emanating from a hearing aid.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(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 Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K061104