Etymonic Design Incorporated
Applied Microelectronics
41 Byron Avenue, Dorchester, Ontario N0L 1G0
Tel: (519) 268-3313 Fax: (519) 268-3256

SEP 2 1 2001

K012306

SECTION E - 510(K) SUMMARY OF SAFETY & EFFECTIVENESS

Audioscan® Verifit™ Model VF-1

Classification Name:	Hearing-Aid Calibrator & Analysis System
Common/Usual Name:	Hearing Aid Analyzer
Proprietary Name:	Audioscan® Verifit™ Model VF-1
Establishment Registration:	8022229
Medical Specialty:	Panel 77, Ear, Nose, & Throat
Product Code:	ETW
Regulation Number:	21 CFR 874.3310
Device Classification:	II
Contact Person:	William A Cole, President

Indications for Use:

The Audioscan® Verifit™ is a hearing aid analysis system that is an electronic reference device used by manufacturers and dispensers of hearing aids intended to calibrate and assess the electroacoustic frequency and sound intensity characteristics emanating from a hearing aid coupled to an ear simulator in a test chamber or a hearing aid when worn by a patient.

Performance Standards Conformance:

1. The VF-1 meets or exceeds the equipment requirements of the following standards: American National Standards Institute, *Methods of Measurement of Real-Ear Performance Characteristics of Hearing Aids*, (ANSI S3.46-1997), American National Standards Institute, New York, 1997, and, American National Standards Institute, *Specification of Hearing Aid Characteristics*, (ANSI S3.22-1996), American National Standards Institute, New York, 1996.

2. The VF-1 meets or exceeds the applicable requirements of the following standards for safety: IEC 60601-1, EN60601-1, UL-2601 and UL 544.

3. The VF-1 meets or exceeds the Food and Drug Administration radiation safety performance standards prescribed in the Code of Federal Regulations, Title 21, Chapter I, Subchapter J.

Substantial Equivalence:

Determination of substantial equivalence of the Audioscan® Verifit™ VF-1 instrument to the currently marketed Audioscan® Real Ear Measurement System RM500, 510(k) No. K884046/A, February 13, 1989, is based on the following safety and effectiveness information:

- The Audioscan® Verifit™ device is manufactured and delivered completely assembled to the health care professional using materials and techniques widely used by other manufacturers of devices as with the predicate device.

- Patient safety is preserved in both the Audioscan® Verifit™ and predicate devices. There is no direct electrical connection to the patient. The silicone probe microphone assembly that has contact with the patient's ear canal during the testing of the hearing aid, has no exposed metal parts and is classed as an F-Type Applied Part in UL2601-1. Thus, there is no possibility of electrical conductance.

- Regarding physical configurations, the system is integrated with the hearing test chamber physically part of the display/control unit in the predicate device, whereas the Audioscan® Verifit™ hearing aid test chamber is physically separated from the display/control unit.

- Software algorithms are essentially equivalent for both the Audioscan® Verifit™ and predicate devices.

- To establish the safety and effectiveness of the software that controls the instrument, the development, verification, validation, and testing procedures are in accordance with FDA guidances for devices containing software.[1,2]. Quality Assurance procedures are adhered to and test results demonstrate that both system specifications and function requirements are met.

[1] Guidance Principles of Software Validation, Draft Guidance Version 1.1, June 9, 1997, Center for Devices and Radiological Health, Food and Drug Administration

[2] ODE Guidance for the Content of Premarket Submission for Medical Devices Containing Software, May 29, 1998, Center for Devices and Radiological Health, Food and Drug Administration

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- The maximum sound level output of the Audioscan® Verifit™ speakers, if used as intended, remains below +90 dB SPL throughout the frequency range of 200 to 8000 Hz. This demonstrates that the Audioscan® Verifit™ unit emits sounds well within OSHA permissible exposure limits of 8 hours at 90 dB. The maximum sound level output of the predicate device speakers is 85 dB SPL if used as intended.

- The signal processing and analysis differ between the Audioscan® Verifit™ and the predicate device. Signals are processed and analyzed by digitally controlled analog amplifiers, attenuators and filters in the predicate device. In the Audioscan® Verifit™, with the exception of the microphone preamplifiers and output amplifiers, all signal processing and analysis is carried out digitally.

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Specification Comparison Table

CHARACTERISTIC	MODEL RM500	VERIFIT™ MODEL VF-1
GENERAL		
Overall dimensions	15.5" x 13.2" x 6.2"	Rear main unit 14.5" x 16" x 6.5" Test chamber 14" x 14.4" x 4"
Weight	15 lbs	16 lbs
Display type	fluorescent backlit blue on white	fluorescent backlit active color
Display size	6.4" diagonal	12.1" diagonal
Display pixels (resolution)	320 x 200 (VGA)	800 x 600 (SVGA)
Printer type	thermal line printer	SAME
Printer resolution	200 dots per inch	SAME
Paper width	3" (80 mm)	SAME
Connectors	1 – external monitor (15HD) 1 – RS232 (9D) 1 – external speaker (RCA) 1 – real-ear/coupler mic. (RJ11)	1 – mouse (PS2-6 pin) 1 - QWERTY keyboard (PS2-6pin) 1 - external monitor (15HD) 1 - parallel printer (25D) 1 - RS232 serial (9D) 1 - ethernet (RJ45) 2 - USB 2 - external speakers (RCA) 2 – external speakers (1/4" mono)) 2 – real-ear mics. (3.5 mm st) 1 – RECD transducer (3.5 mm st) 1 – monitor headset (3.5 mm st) 1 – test chamber ref. mic. (3.5 mm st) 1 – coupler microphone (3.5 mm st) 1 – battery substitute (3.5 mm st)
Headphone monitor amplifier	1 watt into 16 ohms	SAME
Power amplifiers	1 – 1.7 watts	2 - 5 watts each
Stimulus channels	1	2
Measurement channels	2	SAME
HEARING AID TEST CHAMBER		
Working space	5.5" x 3.5" x 2"	8" x 5" x 1.5" (approx.)
Speakers	1 – 3.5" diameter	2 - 2" x 3" independent
Induction coils	1 -Telephone Magnetic Field Simulator (TMFS ANSI S3.22 – 1996) 1 - 20 cm diameter test loop	SAME
Battery simulator	per ANSI S3.22 - 1996	SAME
Frequency range	200 to 8000 Hz	SAME
Test stimuli	tone	tone, broad-band noise, recorded speech

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CHARACTERISTIC	MODEL RM500	VERIFIT™ MODEL VF-1
Test stimulus levels	40 to 90 dB SPL in 5 dB steps	SAME
Test stimulus levels (inductive)	31.6 mA/m per ANSI S3.22 -1996	SAME
Test stimulus distortion	<2% at 90 dB SPL <0.5% at 70 dB SPL	SAME
Test stimulus accuracy at reference microphone for tones (200 – 2000 Hz)	± 1.5 dB SPL	SAME
Test stimulus accuracy at reference microphone for tones (2000 –8000 Hz)	± 2.5 dB SPL	SAME
Equalization method	pressure method	SAME
Analysis frequencies per octave	12	SAME
Analysis filter bandwidth	1/7 octave	1/12 octave
Measurement accuracy at 1 kHz	± 1 dB	SAME
Measurement accuracy re 1 kHz	± 1 dB (200 – 5000 Hz) ± 2.5 dB (5000 – 8000 Hz)	SAME
Measurement range	30 – 140 dB SPL	SAME
Harmonic distortion measurement	2nd plus 3rd	2nd and 3rd or 2nd plus 3rd
Harmonic distortion range	200 to 2670 Hz	200 to 4000 Hz
Harmonic distortion accuracy	± 1%	SAME
Battery drain range	0 – 20 mA	SAME
Battery drain accuracy	± .01 mA	SAME
ANSI S3.22-1996 tests available	➢ OSPL90 ➢ Full-on Gain ➢ Reference Test Gain ➢ Frequency Response ➢ Frequency Range ➢ Maximum OSPL90 ➢ Harmonic Distortion ➢ Attack & Release time ➢ Equivalent Input Noise ➢ Input/Output Curves ➢ Coupler SPL – Telephone Simulator ➢ Simulated Telecoil Sensitivity ➢ Battery drain	SAME With the added features: ➢ Coupler SPL – Vertical Magnetic Field ➢ Test Loop Sensitivity
Other tests available	➢ coupler SPL vs frequency ➢ spectral analysis ➢ manual measurement of output, gain and distortion	SAME With the added features: ➢ coupler gain vs frequency distortion vs frequency
REAL-EAR MEASUREMENT		
Speakers	1 – 3.5" diameter	2 – 2" x 3" ducted ports

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CHARACTERISTIC	MODEL RM500	VERIFIT™ MODEL VF-1
Probe microphone tube	Silicone 1.0mm diameter x 75mm	SAME
Frequency range	200 to 8000 Hz	SAME
Test stimuli	frequency-modulated tone, tone burst, amplitude-modulated tone	frequency-modulated tone, tone burst, broad-band noise, recorded speech
Frequency modulation	triangular ±5% at 36 Hz	SAME
Test stimulus levels at reference microphone for tones at 1 m	40 to 85 dB SPL in 5 dB steps	40 to 90 dB SPL in 5 dB steps
Test stimulus accuracy at reference microphone for tones (200 – 2000 Hz)	± 1.5 dB SPL	SAME
Test stimulus accuracy at reference microphone for tones (2000 –8000 Hz)	± 2.5 dB SPL	SAME
Equalization method	pressure method	SAME
Analysis frequencies per octave	12	SAME
Analysis filter bandwidth	1/7 octave	1/12 octave
Measurement accuracy at 1 kHz	± 1 dB	SAME
Measurement accuracy re 1 kHz	± 1 dB (200 – 5000 Hz) ± 2.5 dB (5000 – 8000 Hz)	SAME
Measurement range	20 –135 dB SPL (200 – 2500 Hz) 30 – 140 dB SPL (2500 – 8000 Hz)	SAME
ANSI S3.46-1997 tests available	➢ Real-Ear Unaided Response ➢ Real-Ear Aided Response ➢ Real-Ear Occluded Response ➢ Real-Ear Insertion Gain	SAME
Other tests available	➢ Real-ear harmonic distortion ➢ Real-ear spectral analysis ➢ manual measurement of output, gain and distortion	SAME
Prescriptive fitting methods available	➢ National Acoustics Labs Revised ➢ Pogo II ➢ Berger ➢ Libby ➢ Desired Sensation Level	SAME

NOTES:
1) The couplers used in the RM500 hearing aid test chamber are also used in the Verifit™ VF-1.
2) The probe tubes used with the RM500 real-ear microphone assembly are also used with the VF-1.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 21 2001

William A. Cole, President
Etymonic Design Incorporated
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Dorchester, Ontario N0L 1G0

Re: K012306
Trade Name: Audioscan Verifit™
Regulation Number: 21 CFR 874.3310
Regulation Name: Hearing Aid Calibrator and Analysis System
Regulatory Class: Class II
Product Code: ETW
Dated: July 20, 2001
Received: July 23, 2001

Dear Mr. Cole

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) 594-4613. 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" (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,

A. Ralph Rosenthal

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

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SECTION D - INDICATIONS FOR USE STATEMENT

Ver/ 3 - 4/24/96

Applicant: Etymonic Design Incorporated

510(k) Number (if known): _____

Device Name: Audioscan® Verifit™

Indications For Use:

The Audioscan® Verifit™ is a hearing aid analysis system that is an electronic reference device used by manufacturers and dispensers of hearing aids intended to calibrate and assess the electroacoustic frequency and sound intensity characteristics emanating from a hearing aid coupled to an ear simulator in a test chamber or a hearing aid when worn by a patient.

James K Kruse Ph.D. 9/17/01
(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K012306

JS

Prescription Use X
(Per 21 CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Optional Format 1-2-96)