K103298

APR - 8 2011

510(k) SUMMARY, ACAM 5

This summary of 510(k) is being submitted in accordance with 21 CFR 807.92.

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Date Prepared: March 3, 2011

Proprietary Name: ACAM® 5 Audiometer System

Common Name: Audiometer

Classification Status: Class II exempt, 21 CFR 874.1050, Audiometer

Subsequent, Classifications: Class II, 21 CFR 874.3310, Hearing Aid Calibrator and Analysis System
Class II, 21 CFR 874.1120, Electronic noise generator for audiometric testing

Regulation Name: Audiometer

Product Code: EWO

Subsequent Product Codes: ETW, ETS

Predicate Device Information:

- Siemens Unity 2 (K# unknown) and Siemens Unity 2 HIA and Probe, K071462

DLC 4/1/11

510(k) SUMMARY, continued

Device Description

ACAM® 5 is an audiometer with optional components for performing Real Ear Measurements (REM) Hearing Instrument Testing (HIT) and loudness scaling. It is intended to aid trained audiologists and hearing aid professionals in the diagnosis of hearing loss and the fitting of hearing aids. As a part of the REM and HIT modules ACAM performs several kinds of signal analysis including root mean squared (RMS), fast Fourier transformation (FFT) and percentile analysis (PA). ACAM® 5 gives an audiologist the ability to use one or any combination of the diagnostic tools recommended by the National Acoustics Laboratory (NAL) and Dr. Richard Seewald (DSL-IO).

Available ACAM® 5 hardware consists of an audiometer with a modular control unit for peripheral components, which include a large or small hearing instrument test box and an *in situ* ear probe for real ear measurement. Headphones for audiometry, bone conduction and loudness scaling, loudspeakers, a microphone and an interrupter switch are available for use with the audiometer.

ACAM®'s operational software meets the international software standards established by the Hearing Instruments Software Manufacturers Association (HIMSA) and the speech recognition standards (ISTS, International Speech Test Signals) established by the European Hearing Instrument Manufacturers Association (EHIMA).

The ACAM® 5 system meets or exceeds the following international standards; IEC 60645, ISO 8253, ISO 16832, ANSI S3.6, ANSI S3.22, EN 60118-0, EN 60118-7, DIN IEC 60118-15, ISO 12124, ANSI S3.43

ACAM® 5 should be operated by individuals with education and training in the field of audiology such as audiologists, hearing aid dispensers, health care and school nurses and ear nose and throat specialists.

Intended Use/Indications for Use

ACAM® 5 is intended as an aid in diagnosing hearing loss and fitting of hearing aids. The device consists of an audiometer that can be used individually or with the other ACAM modules for performing Real Ear Measurements (REM), Hearing Instrument Test (HIT) and loudness scaling. ACAM 5® should be used by persons trained in audiology on patients of any age who are able to understand the basic principles of the test method when explained by the operator.

510(k) SUMMARY, continued

Technological Characteristics

The ACAM® 5 System has substantially the same technological characteristics as the predicate, Siemens Unity 2 audiometer (K# unknown), with the HIA and Probe for use with Unity 2, cleared on June 5, 2007 under K071462.

Similarities

Both the Acousticon ACAM® 5 and the Siemens Unity 2 are modular systems intended for the diagnosis of hearing loss and optimization of the acoustical parameters of hearing aid fitting. Both the ACAM® 5 (applicant) and Siemens (predicate) systems provide modular components that can be used individually or in tandem to support processes from hearing diagnostics to hearing aid fitting. Both the predicate and the applicant systems are computer controlled and include software specific for their applications, including links to the NOAH™ software applications provided by the Hearing Instrument Manufacturers' Software Association (HIMSA™). Both the applicant and the predicate systems utilize Real Ear Measurement (REM) fitting protocols that include percentile measurement to analyze the dynamic feature of amplified speech signals. Both the applicant and the predicate systems allow for the use of fitting protocols provided by the National Acoustic Laboratory (NAL-NL1) and by Dr Richard Seewald (DSL-IO). Both the predicate and applicant systems utilize optional visual stimuli that accompany ambient background sounds. Both the predicate and applicant systems offer ambient sound modules to optimize hearing aid performance in real life situations. Both Systems have an audiometer module to measure hearing losses with pure tone and speech following the requirements of ANSI S3.6.

Differences

The predicate system uses single tone frequency scaling over a range of 125 - 8,000 Hz (normal mode) and 125 - 16,000 Hz (high frequency mode), using mean background noise levels and a fixed signal to noise ratio (SNR), while the applicant system uses single tone frequency scaling over a range of 125 - 8,000 Hz and does not have a high frequency mode. The predicate system offers ambient sounds accompanied by still pictograms (SPL O gram) of environmental surroundings and two speakers, while the applicant system employs video sequences (real life fitting, or RLF sequence) with up to 12 speakers. The applicant system provides a broader menu of ambient sound selections than the predicate system. The predicate integrated system includes hearing aid programming with a Siemens hearing aid. The applicant does not include hearing aid programming.

Comparison to Predicate Device

The ACAM 5 Audiometer is equivalent to the predicate device in intended use its technological characteristics, design and function, as demonstrated in the comparison table below:

510(k) SUMMARY, Comparison to Predicate Device, continued

Table of Similarities and Differences

Device Specifications	Siemens Unity 2, with HIA and Probe		ACAM 5	
K Number	K# unknown, K071462 (HIA and Probe)		K103298	
Intended use	See indications for use		See indications for use	
Indications for use	The Unity 2 is indicated for use in conducting diagnostic hearing evaluations and assisting in the diagnosis of possible otologic disorders. The Unity 2 HIA and Probe are intended to be used as a system to: (1) perform Real Ear Measurement; (2) get an objective indication of the characteristics of a hearing aid; and (3) assist in the adjustment of hearing aids while in use by the patient. It is used by ENT professionals and in clinics for hearing aid fitting. This device can either be sold individually or together with other Unity 2 modules.		ACAM® 5 is intended as an aid in diagnosing hearing loss and fitting of hearing aids. The device consists of an audiometer that can be used individually or with the other ACAM modules for performing Real Ear Measurements (REM), Hearing Instrument Test (HIT) and loudness scaling. ACAM 5® should be used by persons trained in audiology on patients of any age who are able to understand the basic principles of the test method when explained by the operator.	
Target population	Individuals of any age who have demonstrated hearing loss, and who are able to understand and respond to the basic principles of the test method when explained by the operator.		Individuals of any age who have demonstrated hearing loss, and who are able to understand and respond to the basic principles of the test method when explained by the operator	
Anatomical sites	Ear		Ear	
Where used	Clinics and on-site applications		Clinics and on-site applications	
Energy used and/or delivered	**Hz**	**dB HL**	**Hz**	**dB HL**
Air line Headphones	125 250 500 750 1000 1500 2000 3000 4000 6000 8000 10000 12500 16000	100 / 90 110 / 110 115 / 120 120 / 120 120 / 120 115 / 120 115 / 120 115 / 120 115 / 120 105 / 120 110 / 105 / 100 / 90 / 60	125 250 500 750 1000 1500 2000 3000 4000 6000 8000	90 110 120 120 120 120 120 120 120 120 110
Bone line Headphones	125 250 500 750 1000 1500 2000 3000 4000 6000 8000	40 50 70 70 70 70 70 70 60 60 50	125 250 500 750 1000 1500 2000 3000 4000 6000 8000	45 60 70 70 70 70 75 80 80 50 50

510(k) SUMMARY, Comparison to Predicate Device, continued

Table of Similarities and Differences, continued

Device Specifications	Siemens Unity 2 with HIA and Probe		ACAM 5	
Energy used and/or delivered	**Hz**	**dB HL**	**Hz**	**dB HL**
Air Line Speakers	125 250 500 750 1000 1500 2000 3000 4000 6000 8000	80 90 90 90 90 90 90 90 90 80 65	125 250 500 750 1000 1500 2000 3000 4000 6000 8000	68 85 95 95 95 95 95 100 100 95 75
Human factors	Subjective loudness response		Subjective loudness response	
Design	Modular components consisting of: Audiometer and headphones, external speakers, hearing instrument test box and microphone, software		Modular components consisting of: Audiometer and headphones, external speakers, hearing instrument test box and microphone, software	
Testing Features	• Real Ear measurement • Pure tone and speech audiometry • Loudness scaling and noise impulse audiometry • ISTS. International Speech Test Signal • Pediatric audiometry, if requested • Automated fitting report • Percentile analysis		• Real Ear measurement • Pure tone and speech audiometry • Loudness scaling and noise impulse audiometry • ISTS. International Speech Test Signal • Pediatric audiometry, if requested • Automated fitting report • Percentile Analysis	
Available Tests	Audiometer: • Air conduction • Bone conduction • Free field (10 W integrated 2-channel amplifier)		Audiometer: • Air conduction • Bone conduction • Free field 4 Channel Standard (optional up to 12 Channel) with 20W Power	
Tests conducted above hearing threshold	• SISI test • ABLB test (Fowler) • DLI test (Luescher) • Stenger test • Tone decay test (Carhart)		• ABLB test (Fowler) • Stenger test • Tone decay test (Carhart) • Speech Audiometry in quiet and in Noise • ANL(acceptable Noise Level)	
Tests conducted above hearing threshold	• SISI test • ABLB test (Fowler) • DLI test (Luescher) • Stenger test • Tone decay test (Carhart)		• ABLB test (Fowler) • Stenger test • Tone decay test (Carhart) • Speech Audiometry in quiet and in Noise • ANL(acceptable Noise Level)	

510(k) SUMMARY, Comparison to Predicate Device, continued

Table of Similarities and Differences, continued

Device Specifications	Siemens Unity 2 with HIA and Probe	ACAM 5
Additional Tests Offered	• REUR (Real Ear Unaided Response), • OEG (Open Ear Gain) • REOR (Real Ear Occluded Response) • REAR (Real Ear Aided Response, SPL level at the eardrum) • REIG (Real Ear Insertion Gain) • RECD (Real Ear-to-Coupler Difference) • LI/LO (Input-/Output curve) • Sound Mapping • On top mode • Percentile analysis	• REUR (Real Ear Unaided Response), • OEG (Open Ear Gain) • REAR (Real Ear Aided Response, SPL level at the eardrum) • REIG (Real Ear Insertion Gain) • RECD (Real Ear-to-Coupler Difference) • LI/LO (Input-/Output curve) • Percentile analysis
Technical specifications	**Common Data for all Applications:** • Frequency Accuracy: ± 1 % • FFT: Resolution 1024 points, Averaging: 10–100 • Intensity Accuracy: ± 1.5 dB • Sweep Speed: 1.5 - 12 sec./decade at 25 Hz warble frequency (depending on frequency resolution) • Frequency Resolution: 1/3, 1/6, 1/12 and 1/24 octave • Stimulus Distortion: Less than 1 % THD	**Common Data for all Applications:** • Frequency Accuracy: < 1 % • FFT: Resolution 2048 points, Averaging: 10–100 • Intensity Accuracy: ± 1.5 dB • Sweep Speed: 1.5 - 12 sec./decade at 25 Hz warble frequency (depending on frequency resolution) • Frequency Resolution: up to 2048 points between 100Hz and 10kHz • Stimulus Distortion: Less than 1 % THD
Frequency Range	• 125 Hz - 8 kHz (AC & free field) • 125 Hz - 16 kHz (AC, HF mode) • 250 Hz - 6 kHz (BC)	• 125 Hz - 8 kHz (AC & free field) • No HF mode • 125 Hz - 8 kHz (BC)
Stimulus-Signal	• Pure tone, warble, • Noise signals: White, narrow band, speech • ILTASS	• Pure tone, warble, • Noise signals: White, narrow band, speech
Measurement Intensity Range	• AC: -10 - 130 dB HL • BC: -10 - 80 dB HL	• AC: -10 - 120 dB HL • BC: -10 - 70 dB HL
Frequency Range	• 125 Hz - 8 kHz (AC & free field) • 125 Hz - 16 kHz (AC, HF mode) • 250 Hz - 6 kHz (BC)	Audiometry • 125 Hz - 8 kHz (AC, BC & free field) HIT & REM • 100 Hz - 10 kHz
Target gain formulas	NAL-NL1 and DSL i/o; NAL-RP, Berger, Pogo II, 1/3 Gain, 1/2 Gain, Fig6 (K-AMp)	NAL-NL1, DSL i/o, DSL mio; NAL-RP, Berger, Pogo II, 1/3 Gain, 1/2 Gain, Fig6 (K-AMP), IDM, own Rules
Stimulus-Signal:	• Pure tone, warble, • Noise signals: Narrow band, White, Pink, Speech, ILTASS, ICRA, Chirp, patient voice	• Pure tone, warble, CHIRP, Burst • Noise signals: Narrow band, White, Pink, Speech, ICRA, • Real Signals: Speech, ISTS (about 200 live Signals)
Test Intensity Range	Adjustable increments of 1 dB • Speaker: 40 - 100 dB SPL	Adjustable increments of 1 dB • Speaker: 0 - 100 dB SPL • Open headphones: 0 – 100 dB SPL • Insertion Earphones: 40 – 140 SPL

510(k) SUMMARY, Comparison to Predicate Device, continued

Table of Similarities and Differences, continued

Device Specifications	Siemens Unity 2 with HIA and Probe	ACAM 5
Measurement Intensity Range	• Microphone: 40 - 145 dB SPL	• Microphone: <30 to >140 dB SPL
Loudspeaker Output	• Max. 6 W into 8 ohms • Max. 10 W into 4 ohms	• Max. 20 W into 4 ohms
Hearing Instrument Analyzer	• Single measurement (configurable): • OSPL90 • Full On Gain • Input/Output • Attack/Release Time • Reference Test Gain • Frequency Response • Equivalent Input Noise • Harmonic Distortion • Battery Current Drain • Automatic test sequence acc. to EN 60118 or ANSI 3.22 (customizable) • Percentile analysis	• Single measurement (configurable): • OSPL90 • Full On Gain • Input/Output • Attack/Release Time • Reference Test Gain • Frequency Response • Equivalent Input Noise • Harmonic Distortion • Battery Current Drain • Automatic test sequence acc. to EN 60118 or ANSI 3.22 (customizable) • Delay Time (Group Delay) • Percentile analysis • Dynamic Compression Ratio • Long Term Test • Sonogram • Amplitude statistics • Loudness • Roughness • Spectrum of envelope • Intermodulation • Reverberation time • Induction
Loudspeaker:	integrated test box speaker	integrated test box speaker
Hearing Instrument test box Technical specifications		
Telecoil drive in test box	10 - 100 mA/Meter	0.01mA/meter - 1 A/meter
Total Harmonic Distortion	Ranges 0 - 55%, Resolution 0.1 %	Ranges 0 – 100 %, Resolution 0.1 %
Battery-Simulator:	Standard types are selectable, Custom types within 1.1 - 1.6 V,0 - 25 Ohm range	Voltage adjustable 0 to 3V (resolution 0.01Volt)
Battery Current Test:	• Ranges: 0 - 50 mA • Resolution: 0.1 mA • Accuracy: ± 5 %	• Ranges: 0 - >20 mA • Resolution: 0.01 mA • Accuracy: ± 5 %
Computer Communication:	Built-in USB1.1 computer interface. Windows software available	Network Protocol TCP/IP over Twisted Pair (Standard Network Interface)
Supported Operating systems:	Windows 98 SE and higher (except Windows NT)	Windows XP SP3

510(k) SUMMARY, Comparison to Predicate Device, continued

Table of Similarities and Differences, continued

Device Specifications	Siemens Unity 2 with HIA and Probe	ACAM 5
Construction	Anodized all-aluminium case.	Industry 19" Rack
Power Fuses	AC 50/60 Hz, 100 - 240V, 5 x 20 mm, 2.15 AT	AC 50/60 Hz, 100 - 240V, 2 X 1 AT
Consumption	75 W	110W
Dimensions (cm)	• Control Unit: 31.9L x 31.7W x 7.5H • Docking Station: 42.8L x 23.0X x 22.2H	• Control Unit: 36L x 36.5W x 14H • Open Test Box, Small: 20L x 20X x 12H • Closed Test Box, Large: 40L x 33 x 30H
Standards Met	Audiometer EN 60645-1 EN 60645-2 EN 60645-4 ANSI S3.6 ANSI S3.22 Hearing Instrument Analyzer EN 60118-0 EN 60118-7 ANSI S3.43	Audiometer EN 60645-1 EN 60645-2 ISO 8253 – 1,2,3 ISO 16832 ANSI S3.6 ANSI S3.22 Hearing Instrument Analyzer EN 60118-0 EN 60118-7 ISO 12124 ANSI S3.43
Materials	NA	NA
Biocompatibility	NA	NA
Compatibility with the environment and other devices	NA	NA
Sterility	NA	NA
Electrical safety	EN 60601-1, Class 1, Type B EN 60601-1-2	EN 60601-1, Class 1, Type B EN 60601-1-2
Mechanical safety	NA	NA
Chemical safety	NA	NA
Thermal safety	NA	NA
Radiation safety	NA	NA

510(k) SUMMARY, Performance Test Data and Conclusions

Performance Test Data and Conclusions

As is the case with the predicate device, the ACAM system was subjected to electrical safety and electromagnetic compatibility testing and performance specifications and was found to be in compliance with the requirements of the international consensus standards shown below. Conformity with the requirements of these standards demonstrates that the ACAM System is safe and effective and is substantially equivalent to the predicate device.

Safety:

The ACAM System has been designed, constructed and tested to meet the safety and performance requirements of various national safety codes and standards. The ACAM System complies with the following international safety standards:

- EN 60601-1 1996-03 Medical electrical equipment; Part 1: General requirements for safety; (FDA Recognition # 5-4)
- EN 60601-1-1:2001 Medical electrical equipment; Part 1-1: General requirements for safety; 1.Collateral standard: Safety requirements for medical electrical systems (FDA Recognition # 5-27)
- EN 60601-1-2:2001 Medical electrical equipment; Part 1: General requirements for safety; 2.Collateral standard: Electromagnetic compatibility - Requirements and tests (FDA Recognition # 5-30)

Effectiveness:

The effectiveness of the ACAM System has been shown through testing in accordance with the following international standards:

- ANSI S3.6-2004, Specification for Audiometers, (FDA Recognition # 4-123)
- ANSI S3.46-1997(R2007), Methods of Measurement of Real-Ear Performance Characteristics of Hearing Aids (FDA Recognition # 4-175)
- ANSI S3.22-2003, Specification of Hearing Aid Characteristics (FDA Recognition # 4-124)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Acousticon GmbH
c/o Ms. Maureen N. Garner
President
New World Regulatory Solutions, Inc.
P.O. Box 5374
Toms River, NJ 08754

APR = 8 2011

Re: K103298
Trade/Device Name: ACAM® 5 Audiometer System
Regulation Number: 21 CFR 874.1050
Regulation Name: Audiometer
Regulatory Class: Class II
Product Code: EWO
Dated: March 25, 2011
Received: March 29, 2011

Dear Ms. Garner:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

K103298

INDICATIONS FOR USE

510(k) Number K103298

Device Name: ACAM® 5

Indications for Use: ACAM® 5 is intended as an aid in diagnosing hearing loss and fitting of hearing aids. The device consists of an audiometer that can be used individually or with the other ACAM modules for performing Real Ear Measurements (REM), Hearing Instrument Test (HIT) and loudness scaling. ACAM 5® should be used by persons trained in audiology on patients of any age who are able to understand the basic principles of the test method when explained by the operator.

Prescription Use (Part 21 CFR 801 Subpart D) ____X____ AND/OR Over-The-Counter Use (21 CFR 807 Subpart C) _____

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K103298