510(K) Summary, 510(k) K122028

Submitter: GN Otometrics A/S
Hoerskaetten 9 Taastrup,
DENMARK DK-2630
Registration number: 9612197
C/O GN Otometrics North America
50 Commerce Dr Ste 180
Schaumburg, IL 60173
(US) Phone: 847-534-2150
(US) Fax: 847-534-2153
Contact: Dan Sansonetti, Manager of Research and Development
Date Prepared: October 16, 2012

OCT 23 2012

1. **Identification of the Device:**
   Proprietary-Trade Name: **Aurical HIT Type 1082**
   Classification Name: Calibrator, hearing aid / earphone and analysis systems, Class II
   Common/Usual Name: Hearing aid calibrator

2. **Product code:** ETW

3. **Equivalent legally marketed devices**: 510(K) Number K113831 PRIMUS HEARING INSTRUMENT TEST UNIT, AUDITDATA A/S.

4. **Description of the Device**: AURICAL HIT is designed for Hearing Instrument Testing and Coupler-Based Fitting. AURICAL HIT connects via USB to a computer running the OTOsuite software. With the OTOsuite HIT Module one can perform traditional hearing instrument testing according to either the ANSI or IEC test protocols, and obtain a consistent picture of every hearing instrument, regardless of manufacturer or type. With the OTOsuite PMM Module one can perform Probe Microphone Measurements in a coupler for pre-programming and pre-fitting hearing instruments without the client being present. It is easy to position hearing instruments on snap-on couplers inside the AURICAL HIT test chamber and it is easy to access the hearing instruments in the test chamber during test without disturbing the test setup. The battery pill types are recognized automatically, and the reference microphone ensures reliable positioning in the test chamber.

5. **Indications for Use** (intended use): The Aurical HIT Type 1082 is intended to be used by audiologists, technicians, and other professionals who perform hearing instrument testing. Used in conjunction with the OTOSuite software, the Type 1082 permits presentation of acoustic sounds and magnetic field stimuli in order to assess the audio processing and telecoil functionality of the hearing instrument.

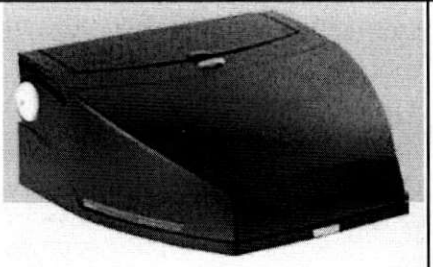
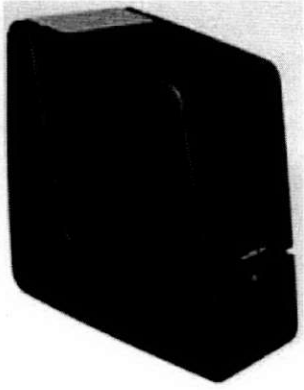
6. **Safety and Effectiveness, comparison to predicate device**. This device has the same indications for use as the predicate device and employs similar technology to accomplish the same tasks.

7. **Description of Testing:** Testing consisted of non-clinical performance testing of the device against the applicable parameters specified in the following standards: ANSI S3.22: 2003, and IEC 60118-7:2005 The device passed UL Electrical Safety (IEC 61010-1) testing and EMC (IEC 61326-1) testing. Software validation and risk analysis was performed.

8. Substantial Equivalence Chart

Characteristic	Auditdata Primus K113831	Aurical HIT Type 1082
Intended Use:	Hearing Aid Testing	Hearing Aid Testing
Hearing-aid test-box characteristics:		
Tests	OSPL90 Full on gain Input/Output Attack/Recovery time Reference test gain Frequency response Equivalent input noise Harmonic distortion Battery current drain TeleCoil	OSPL90 & HFA-OSPL90 Full on gain Input/Output Attack/Recovery time Reference test gain Frequency response Equivalent input noise Harmonic distortion Battery current drain TeleCoil
Test Level Range:	50 - 90 dB SPL	40 - 100 dB SPL
Freq. Range	125 Hz - 8 kHz	125 - 10,000 Hz
Standards met for Hearing Instrument Testing	ANSI S3.22 IEC 60118-7	ANSI S3.22: 2003 IEC 60118-7: 2005
Electrical Safety	IEC 60601-1, Class 1, Type B	IEC 61010-1
EMC	IEC 60601-2	IEC 61326-1
Power supply	USB, and external power supply for elevated outputs	USB Max. 2.5 W
Communication port	USB 2	USB 2.0
PC minimum requirements	CPU Minimum 1.4 GHz processor with 512 MB (1 GB recommended) system RAM Harddisk space 1 GB free harddisk space for Primus Operating system Windows XP Professional SP2 (32-bit), Windows Vista (32-bit) including: Vista Home Basic, Vista Home Premium, Vista Business, Vista Enterprise and Vista Ultimate, Windows 7 (32-bit) including Windows 7 Home Premium, Windows 7 Professional and Windows 7 Ultimate Graphics card 1024 x 768. XVGA Connections CD drive and USB 2.0 connection required	1.5 GHz processor or higher (2 GHz recommended) • 512 MB RAM (1 GB recommended) for Windows XP, or 1 GB (1.5 GB recommended) for Windows Vista and Windows 7 • 2.5 GB free disk space for installation of the OTOsuite software. Additional disk space is needed for installation of prerequisites • Windows® XP (32 bit) with SP3 or higher, or Windows Vista (32 bit) with SP2, or Windows 7 (32 or 64 bit) • USB port for connecting accessories, v. 1.1, or 2.0 • DVD or CD-ROM drive • 32 bit color display, 1024x768 screen resolution • 32 MB graphic memory • Windows-compatible sound card • Supports NOAH 3.5, NOAH 3.5 for ENTs, or higher, for NOAH mode operation.

K122028

Characteristic	Auditdata Primus K113831	Aurical HIT Type 1082
Photo		

9. **Conclusion:** The Aurical HIT Type 1082 meets applicable standards for hearing instrument testers: ANSI S3.22: 2003 and IEC 60118-7: 2005. Per the bench performance testing, software testing, and safety testing, we conclude that the Aurical HIT Type 1082 is as safe and effective as the predicate device, and has essentially the same indications for use, thus rendering it substantially equivalent to the predicate device.

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

OCT 23 2012

GN Otometrics A/S
c/o Daniel Kamm, P.E.
Regulatory Engineer, Submission Correspondent
Kamm & Associates
8870 Ravello Ct.
Naples, FL 34114

Re: K122028
Trade/Device Name: Aurical HIT
Regulation Number: 21 CFR 874.3310
Regulation Name: Hearing aid calibrator and analysis system
Regulatory Class: Class II
Product Code: ETW
Dated: September 11, 2012
Received: September 21, 2012

Dear Mr. Kamm:

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

K122028

Indications for Use

510(k) Number (if known): K122028

Device Name: Aurical HIT Type 1082

Indications For Use:

The Aurical HIT Type 1082 is intended to be used by audiologists, technicians, and other professionals who perform hearing instrument testing. Used in conjunction with the OTOSuite software, the Type 1082 permits presentation of acoustic sounds and magnetic field stimuli in order to assess the audio processing and telecoil functionality of the hearing instrument.

Prescription Use _X_ AND/OR Over-The-Counter Use ____(Part 21 CFR 801 Subpart D) (21 CFR 807 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, Neurological and Ear, Nose and Throat Devices

510(k) Number K122028