FEB 2 7 2014

510(K) Summary, 510(k) K132957

Submitter: GN Otometrics A/S
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Date Prepared: February 20, 2014

Identification of the Device:
Proprietary-Trade Name: MADSEN AccuScreen Type 1077
Classification Name: Stimulator, Auditory, Evoked Response
Common/Usual Name: Auditory Evoked Response Stimulator.
Product code: GWJ
Classification Panel: Neurology
Device Class: Class II
FDA CFR Section: FDA 21CFR 882.1900

Equivalent legally marketed devices:

Predicate Devices		
Product Name:	Echo-Screen T, TA, TD, TDA, TC	Type 1077 AccuScreen
510(k) Number:	K013977	K122067
Classification Name:	Stimulator, Auditory, Evoked Response	Stimulator, Auditory, Evoked Response
FDA CFR Section:	FDA 21CFR 882.1900	FDA 21CFR 882.1900
Device Product Code:	GWJ	GWJ
Manufacturer Name:	Fischer-Zoth Audiologic Systems	GN Otometrics

Description of the Device: The device is identical to our own device described in K122067. Only the indications for use has changed. The age range has been expanded. Different models of the device are capable of the following list of tests:

Device type	Test types
AccuScreen TE	TEOAE (Transiently Evoked Otoacoustic Emissions)
AccuScreen DP	DPOAE (Distortion Product Otoacoustic Emissions)
AccuScreen TE/DP	TEOAE and DPOAE
AccuScreen ABR	ABR (Auditory Brainstem Response)
AccuScreen ABR/TE	ABR and TEOAE
AccuScreen ABR/DP	ABR and DPOAE
AccuScreen ABR/TE/DP	ABR, TEOAE and DPOAE

The measurement application is controlled from a self-contained firmware (software) module installed in the handheld device. The firmware module can be configured to allow different OAE measurement types (DPOAE and/or TEOAE) by a license key stored in the device.

For automated OAE measurements, the handheld device uses an OAE probe, designed and manufactured by PATH Medical GmbH. The OAE probe has been granted marketing clearance by the

FDA following the submission of a 510(k) (K100661).The OAE probe is fitted with an ear-tip (constructed of biocompatible material) and inserted in the ear canal of the patient. The AccuScreen device plays stimulus sounds in the ear canal via small speakers in the OAE probe. The AccuScreen device measures the patient's response to the stimulus sounds via a microphone in the probe. The measured response is processed by the AccuScreen device using statistics to help determine whether or not a hearing loss may be present.

When the OAE measurement is a DPOAE measurement, the stimulus signal is composed of two pure tone signals, each presented by a speaker in the OAE probe. When the OAE measurement is a TEOAE measurement, the stimulus signal is a series of broadband clicks presented by one speaker in the OAE probe.

While the device has not changed from our 2012 510(k) submission K122067, the target population has been expanded as described in the indications statement directly below:

Indications for Use:
The Type 1077 device is indicated for use in the recording and automated analysis of human physiological data (screening auditory brainstem responses and/or otoacoustic emissions) necessary for the diagnosis of auditory and hearing-related disorders.

Distortion Product Otoacoustic Emissions and Transient Evoked Otoacoustic Emissions:
The Type 1077 DPOAE module and TEOAE module can be used for patients of all ages, from children to adults, including infants and geriatric patients. It is especially indicated for use in testing individuals for whom behavioral audiometric results are deemed unreliable, such as infants, young children, and cognitively impaired adults.

Auditory Brainstem Response:
The Type 1077 ABR module is especially intended for infants from 34 weeks (gestational age) up to 6 months of age.

When the device is used to screen infants, they should be asleep or in a quiet state at the time of screening. The device is intended for use by audiologists, ENT's and other healthcare professionals..

Safety and Effectiveness, comparison to predicate device. This device has the same indications for use as the predicate device K013977and employs similar technology to accomplish the same tasks. The device is identical to our product described in K122067 except for the indications statement. We have expanded the subject population to include persons of all ages. A detailed comparison table is provided below.

Substantial Equivalence Chart

	Echo-Screen T, TA, TD, TDA, TC, Fischer-Zoth Audiologic Systems K013977	MADSEN AccuScreen Type 1077 K122067	MADSEN AccuScreen Type 1077
Indications for Use:	The Fischer-Zoth Audiologic Systems model family Echo-Screen T consisting of Echo-screen T, Echo-Screen TA, Echo-Screen TD, Echo-Screen TDA and Echo-Screen TC are based upon Otoacoustic Emissions (OAE) and Auditory Brainstem Response (ABR) technology. The device is intended to screen hearing for newborns through adults, including geriatric patients. The device does not measure hearing per se, but helps to determine whether or not a hearing loss may be present. The "Echo-Screen T" product family consists of handheld, automated OAE and ABR based hearing screening systems which are easy to use. The measurement flow is menu guided and the evaluation is based upon signal statistics. The "Echo-Screen T" devices are intended to be used by trained personnel in a medical or school environment. The "Echo-Screen T" models are not intended for fitting assistive listening devices such as hearing aids or cochlear implants.	AccuScreen is a portable instrument used to screen infants for hearing loss. The instrument uses the Distortion Product Otoacoustic Emissions (DPOAE), Transient Evoked Otoacoustic Emissions (TEOAE) and Auditory Brainstem Response (ABR) technologies. The instrument is intended for screening infants from 34 weeks (gestational age) up to 6 months of age that are well enough to be ready for discharge from the hospital. Infants should be asleep or in a quiet state at the time of screening. AccuScreen is intended for use by audiologists, ENTs and other health care professionals.	The Type 1077 device is indicated for use in the recording and automated analysis of human physiological data (screening auditory brainstem responses and/or otoacoustic emissions) necessary for the diagnosis of auditory and hearing-related disorders. Distortion Product Otoacoustic Emissions and Transient Evoked Otoacoustic Emissions: The Type 1077 DPOAE module and TEOAE module can be used for patients of all ages, from children to adults, including infants and geriatric patients. It is especially indicated for use in testing individuals for whom behavioral audiometric results are deemed unreliable, such as infants, young children, and cognitively impaired adults. Auditory Brainstem Response: The Type 1077 ABR module is especially intended for infants from 34 weeks (gestational age) up to 6 months of age. When the device is used to screen infants, they should be asleep or in a quiet state at the time of screening. The device is intended for use by audiologists, ENT's and other healthcare professionals.
Config-uration	Hand held battery operated, rechargeable battery	Hand held battery operated, rechargeable battery	Hand held battery operated, rechargeable battery

	Echo-Screen T, TA, TD, TDA, TC, Fischer-Zoth Audiologic Systems K013977	MADSEN AccuScreen Type 1077 K122067	MADSEN AccuScreen Type 1077
Photo			
Tests Performed	DPOAE, TEOAE, ABR	SAME	SAME as MADSEN AccuScreen Type 1077 K122067
Weight	Echo-Screen including battery pack and probe: 550g (1.2 lbs)	240 g (8.5 oz) excluding battery 280 g (9.9 oz) including battery	SAME as MADSEN AccuScreen Type 1077 K122067
Size	Echo-Screen incl. battery pack: 230 x 95 x 53 mm (9.06 x 3.74 x 2.09 inches)	202 x 73 x 30 mm (8 x 2.8 x 1.2 inches)	SAME as MADSEN AccuScreen Type 1077 K122067
Battery	6V 1500mAh NiMH, exchangeable	Rechargeable Li-ion 3.7 V/1800 mAh (6.7 Wh), fully charged	SAME as MADSEN AccuScreen Type 1077 K122067
Operating time	> 10 hrs with fully charged battery	8 hours of continuous use (based on a typical use scenario. Actual use can influence the battery life time.)	SAME as MADSEN AccuScreen Type 1077 K122067
Display	128 x 64 dot graphic LCD w/ switchable backlight	Color, TFT, touch screen, Dimensions: 89.4 mm (3.5 inches) Resolution: 240 x 320 pixels Backlight type: LED, adjustable	SAME as MADSEN AccuScreen Type 1077 K122067
Data memory	128 kB built-in flash memory, unlimited storage time	Patient memory capacity: Max. 250 patients Test memory capacity: Min. 500 tests	SAME as MADSEN AccuScreen Type 1077 K122067
Interfaces	RS232 up to 115 kbps, infrared (optional modem feature available)	IR data transmission to docking station - USB interface from docking station to PC	SAME as MADSEN AccuScreen Type 1077 K122067

	Echo-Screen T, TA, TD, TDA, TC, Fischer-Zoth Audiologic Systems K013977	MADSEN AccuScreen Type 1077 K122067	MADSEN AccuScreen Type 1077
Safety standards	EN 60601-1 + A1 + A2 EN 60601-1-2 EN 60601-2-26 EN 60601-2-40	• EN 60601-1, Internally Powered, Type BF, IPXO • U2601-1; CAN/CSA-C22.2 NO 601.1-90, • IEC 60601-2-26 • IEC 60601-2-40 EMC: EN 60601-1-2	SAME as MADSEN AccuScreen Type 1077 K122067

Summary of non-clinical testing: (Performed in K122067): Standards testing demonstrated compliance with the safety standards in the table above, as well as:
ISO 10993-5 Biological Evaluation of Medical Devices: Tests for Cytotoxicity
ISO 10993-10 Biological Evaluation f Medical Devices: Tests for Irritation and delayed-type hypersensitivity
ISO 10993-1 Biological Evaluation of Medical Devices: Evaluation and Testing
ISO 10993-12 Biological Evaluation of Medical Devices: Sample Preparation and Reference Materials
Bench testing also demonstrated compliance with system hardware and software specifications. A revised risk analysis was also conducted.

Summary of clinical testing: Clinical testing was performed to confirm that the Type 1077 can produce valid results in patients of all age groups and performed in a comparable manner to the predicate Echo-Screen, Fischer-Zoth Audiologic Systems K013977. Subjects were tested on Type 1077 and again on the Echo-Screen. The goal was to test and compare a minimum of 16 ears per age group. Overall 130 ears were tested and compared, with overall DPOAE agreement of 93.8% and TEOAE agreement of 91.5%. The results are shown below.

Age	6 mo–9 y	10-19 y	20-39 y	40-59 y	>59 y	Total
Number of ears recommended	20	20	20	20	20	100
Achieved/tested	26	22	30	36	16	130
DPOAE agreement	26/26 (100.0 %)	22/22 (100.0 %)	30/30 (100.0 %)	33/36 (91.7 %)	11/16 (68.8 %)	122/130 (93.8 %)
TEOAE agreement	26/26 (100.0 %)	22/22 (100.0 %)	30/30 (100.0 %)	30/36 (83.3 %)	11/16 (68.8 %)	119/130 (91.5 %)

After identifying that there were some discrepant results between our device and the predicate device, (40-59 y & >59 y age groups) we used a diagnostic OAE device to re-test all test subjects for which there was not a match between the Type 1077 and predicate device. Our intent was to determine which of the two devices (Type 1077 or Predicate) provided the correct result. After performing the diagnostic OAE testing, we discovered that the predicate device was found to have provided incorrect results in 11 of the 19 cases. Overall the results showed that the Type 1077 performed in a comparable manner to the Echo-Screen on the expanded patient population shown in the revised indications for use.

Conclusion: After analyzing bench testing, safety, EMC, software, and clinical validation testing we conclude that the MADSEN AccuScreen Type 1077 (with expanded indications for use) is as safe and effective as the predicate device, and has essentially the same technological characteristics, thus rendering it substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

February 27, 2014

GN Otometrics A/S
c/o Daniel Kamm, P.E.
8870 Ravello Ct.
Naples, FL 34114

Re: K132957
Trade/Device Name: Madsen accuscreen type 1077
Regulation Number: 21 CFR 882.1900
Regulation Name: Evoked Response Auditory Stimulator
Regulatory Class: Class II
Product Code: GWJ
Dated: January 20, 2014
Received: January 28, 2014

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,

Eric A. Mann -S

for 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K132957

Device Name
MADSEN AccuScreen Type 1077

Indications for Use *(Describe)*
The Type 1077 device is indicated for use in the recording and automated analysis of human physiological data (screening auditory brainstem responses and/or otoacoustic emissions) necessary for the diagnosis of auditory and hearing-related disorders.

Distortion Product Otoacoustic Emissions and Transient Evoked Otoacoustic Emissions:
The Type 1077 DPOAE module and TEOAE module can be used for patients of all ages, from children to adults, including infants and geriatric patients. It is especially indicated for use in testing individuals for whom behavioral audiometric results are deemed unreliable, such as infants, young children, and cognitively impaired adults.

Auditory Brainstem Response:
The Type 1077 ABR module is especially intended for infants from 34 weeks (gestational age) up to 6 months of age.

When the device is used to screen infants, they should be asleep or in a quiet state at the time of screening.
The device is intended for use by audiologists, ENT's and other healthcare professionals.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Shuchen Peng -S

Digitally signed by Shuchen Peng -S
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