DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

September 1, 2016

Gn Otometrics
Mr. Daniel Kamm
Principal Engineer
Kamm & Associates
8870 Ravello Ct.
Naples, FL 34114

Re: K161707
Trade/Device Name: Madsen Zodiac
Regulation Number: 21 CFR 874.1090
Regulation Name: Auditory Impedance Tester
Regulatory Class: Class II
Product Code: ETY
Dated: August 4, 2016
Received: August 9, 2016

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 and Part 809); 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 and Part 809), please contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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

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 below.

510(k) Number *(if known)*
K161707

Device Name
Madsen Zodiac Model 1096 (SA or PC)

Indications for Use *(Describe)*
The Madsen Zodiac (Type 1096) is an auditory impedance tester that is intended to change the air pressure in the external auditory canal and measure and graph the mobility characteristics of the tympanic membrane to evaluate the functional condition of the middle ear. This device is also used to measure the acoustic reflex threshold and decay testing as well as eustachian tube function testing for intact and perforated tympanic membranes.
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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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) Summary, 510(k) K161707

Submitter: GN Otometrics A/S
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Contact: Asif Muhammad, Global Director RA/QA
Date Prepared: June 16, 2016

1. Identification of the Device: 510(k) Number K161707

Proprietary-Trade Name:	**Madsen Zodiac 1096 (SA or PC)**
Common Name:	Tester, Auditory Impedance
Classification Name:	Auditory impedance tester.
Product Code:	ETY
Regulation Number	874.1090

2. Equivalent legally marketed device: 510(K) Number. K033645

Proprietary-Trade Name:	OTOflex 100 Type 1012, GN Otometrics A/S.
Common Name:	Tester, Auditory Impedance
Classification Name:	Auditory impedance tester.
Product Code:	ETY
Regulation Number	874.1090

3. Description of the Device: The MADSEN Zodiac Type 1096 device is designed to measure and evaluate the acoustic impedance/admittance of the human ear by means of acoustic probe signals at different frequencies and with temporal characteristics. MADSEN Zodiac is a compact device for immittance testing. You can operate Zodiac as a stand-alone unit using the built-in keypad and display, or, if you are using the OTOsuite Immittance software module, you can operate Zodiac using the PC's keyboard and mouse with the OTOsuite Immittance module acting as the display.

MADSEN Zodiac supports the following probes:

- The hand-held Quick Check probe
- The two diagnostic probe types, Classic and Comfort
- A contralateral insert phone or TDH-39.

Supported tests: Depending on the configuration, Zodiac supports the following tests and functionalities:

- Tympanometry
- Reflex Screening
- Reflex Threshold
- Reflex Decay
- ETF-I (Eustachian Tube Function - Intact) • ETF-P (Eustachian Tube Function - Perforated)

• Admittance Recording (multiple uses, e.g. patulous Eustachian Tube evaluation, acoustic reflexes with external stimulus)
• Manual Tympanometry
This is a MODIFIED version of our previous model, the predicate device.

4. **Indications for Use** (intended use): The Madsen Zodiac (Type 1096) is an auditory impedance tester that is intended to change the air pressure in the external auditory canal and measure and graph the mobility characteristics of the tympanic membrane to evaluate the functional condition of the middle ear. This device is also used to measure the acoustic reflex threshold and decay testing as well as eustachian tube function testing for intact and perforated tympanic membranes. (Prescription Use).

5. **Technological Characteristics**. This device has the same indications for use as the predicate device and employs similar technology to accomplish the same tasks. Modifications to the cleared device are not substantial and do not change the operating principles of the device. The intended use and fundamental technological characteristics remain the same as the predicate device and modifications do not affect the safety or effectiveness of the device.

6. Substantial Equivalence Chart

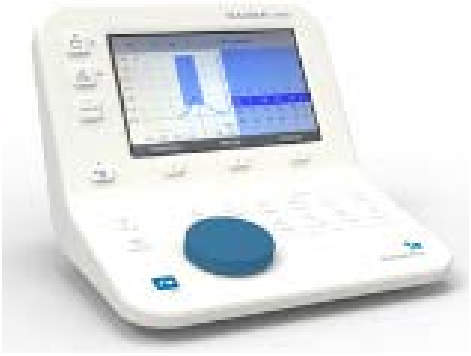
Characteristic	K033645, OTOflex 100 Type 1012, GN Otometrics A/S.	K161707 Madsen Zodiac 1096 GN Otometrics A/S
Intended Use:	The OTOflex 100 Type 1012 is an auditory impedance tester that is intended to change the air pressure in the external auditory canal and measure and graph the mobility characteristics of the tympanic membrane to evaluate the functional condition of the middle ear. This device is also used to measure the acoustic reflex threshold and decay testing as well as eustachian tube function testing for intact and perforated tympanic membranes. (Prescription Use).	The Madsen Zodiac (Type 1096) is an auditory impedance tester that is intended to change the air pressure in the external auditory canal and measure and graph the mobility characteristics of the tympanic membrane to evaluate the functional condition of the middle ear. This device is also used to measure the acoustic reflex threshold and decay testing as well as eustachian tube function testing for intact and perforated tympanic membranes. (Prescription Use). (SAME)
User population	Audiologists, ENTs and other health care professionals in testing the hearing of infants, children and adults.	Same as predicate
Distribution	ENT Doctors, Audiologists and professional Hearing Aid dispensers.	Same as predicate
Energy delivered	Acoustic stimuli: Air pressure stimuli -600daPa to +400daPa	Same as predicate

Characteristic	K033645, OTOflex 100 Type 1012, GN Otometrics A/S.	K161707 Madsen Zodiac 1096 GN Otometrics A/S
Where used	Hospitals, private clinics and Hearing Aid dispensers	Same as predicate
Instructions	The predicate devices functionality is covered by a user's manual.	Same as predicate
Compliance measuring system Probe tones	226 Hz at 85dB SPL ± 1.5 dB 1000Hz at 75dB SPL ± 1.5 dB THD: < 3% in 2 cc Frequency accuracy: ±0.5% Range: 0.1 ml to 8.0 ml ± 5% or 0.1 ml, whichever is greater	226 Hz at 85 dB SPL ± 3 dB 678 Hz at 72 dB SPL ± 3 dB 800 Hz at 70.5 dB SPL ± 3 dB 1000 Hz at 69 dB SPL ± 3 dB THD: < 1% in 2 cc Frequency accuracy: ± 0.5% Range: 0.2 ml to 5.0 ml ± 5% or 0.05 ml which ever is greater, 5 ml to 8.0 ml ± 15%
Acoustic reflex		
Contralateral Stimulation	Pure tones: 500 Hz, 1000 Hz, 2000 Hz, 3000 Hz, 4000 Hz	Same as predicate
	Frequency accuracy: ± 0.5%	Same as predicate
	Noise White Noise according to IEC 61027	Broad Band Noise according to IEC 60645-5
	Low Pass 400 to 1600 Hz.	Low Pass: TDH-39: 250 - 1600 Hz, Insert: 400 - 1600 Hz.
	High Pass 1600 to 4000 Hz.	High Pass: TDH-39: 1600 - 6000 Hz, Insert: 1600 - 4000 Hz.
	Roll off >12 dB/Octave.	Same as predicate
	Range at: BBN, LPN at 50 to 100 dB SPL ±3 dB, HPN at 50 to 95 dB SPL ±3 dB	Range: BBN, LPN, HPN at 50 to 110 dB SPL ±3 dB
	Step size dB 1, 2, 5, 10 dB	Same as predicate
	E-A-RTONE® 3A:	*Contralateral insert phone:*
	Range at: 500 Hz at 50 to 105 dB HL ± 3 dB	Range: 500 Hz at 50 to 115 dB HL ± 3 dB
	1000 Hz at 50 to 120 dB HL ± 3 dB	Same as predicate
	2000 Hz at 50 to 115 dB HL ± 3 dB	2000 Hz at 50 to 120 dB HL ± 3 dB
	3000 Hz at 50 to 105 dB HL ± 3 dB	Frequency not used
	4000 Hz at 50 to 110 dB HL ± 3 dB	4000 Hz at 50 to 120 dB HL ± 3 dB
	THD: < 3% in 2 cc (measured 5 dB below max output)	THD: < 5% for levels below 110 dB HL, < 10% for levels above 110 dB HL
		Contralateral TDH-39 phone:
		500 Hz at 50 to 115 dB HL ± 3 dB
		1000 Hz at 50 to 120 dB HL ± 3 dB
		2000 Hz at 50 to 115 dB HL ± 3 dB

Characteristic	K033645, OTOflex 100 Type 1012, GN Otometrics A/S.	K161707 Madsen Zodiac 1096 GN Otometrics A/S
		4000 Hz at 50 to 115 dB HL ± 3 dB
		< 2.5 % for levels below 110 dB HL
		< 5 % for levels above 110 dB HL
Ipsilateral Stimulation	Tone: 500 Hz, 1000 Hz, 2000 Hz, 3000 Hz, 4000 Hz	Tone: 500 Hz, 1000 Hz, 2000 Hz, 4000 Hz
	Frequency accuracy: ± 0.5%	Same as predicate
	Noise White Noise according to IEC 61027	Broad Band Noise according to IEC 60645-5
	Low Pass 400 to 1600 Hz	Same as predicate
	High Pass 1600 to 4000 Hz	Same as predicate
	Roll off >12 dB/Octave	Same as predicate
	Step size dB: 1, 2, 5, 10 dB	Same as predicate
	Range at: 500 Hz at 50 to 105 dB HL ± 3 dB	Same as predicate
	1000 Hz at 50 to 120 dB HL ± 3 dB	1000 Hz at 50 to 110 dB HL ± 3 dB
	2000 Hz at 50 to 115 dB HL ± 3 dB	2000 Hz at 50 to 110 dB HL ± 3 dB
	3000 Hz at 50 to 105 dB HL ± 3 dB	Frequency not used
	4000 Hz at 50 to 110 dB HL ± 3 dB	4000 Hz at 50 to 100 dB HL ± 3 dB
	THD: < 3% in 2 cc (measured 5 dB below max output)	THD: < 5% for levels below 110 dB HL, < 10% for levels above 110 dB HL
Air pressure system	Range: Normal +200 to -400 daPa/s. Extended +400 to -600 daPa/s	Same as predicate
	Pressure sweep rate: 50, 100, 200, 400 daPa/s, A.F.A.P	Pressure sweep rate: 50, 100, 200, 400, 600 daPa/s
	Pressure accuracy: ±10% or ±10 daPa, whichever is greatest	Same as predicate
	Pump measure direction: Positive to negative or negative to positive	Same as predicate
	Safety: Separate safety +530 daPa and -730 daPa. ±70 daPa	Same as predicate
	Software safety +450 daPa and -650 daPa. ±70 daPa.	Same as predicate
		Manual control of pressure
Graph units	Unit of admittance graph Y-axis: ml, cc, mmho, µl	Same as predicate
	Unit of graph X-axis: daPa, sec	Same as predicate
Device display	Graphic 128x128 dots	Display: 7 inch, 15:9 WVGA Resolution: 800 x 480 pixel
Light indications		Light indication on probes
Interface	Wireless Bluetooth data transfer to	Type: USB device port

Characteristic	K033645, OTOflex 100 Type 1012, GN Otometrics A/S.	K161707 Madsen Zodiac 1096 GN Otometrics A/S
	PC	Compatible: USB 2.0
Operating environment	Temperature: +15°C to +35°C (59°F to +95°F)	Same as predicate
	Rel. humidity: 30 to 90 %, non-condensing	Same as predicate
	Warm-up time: < 2 min.	Warm-up time: < 10 min.
	Air pressure: 600 hPa to 1060 hPa	Same as predicate
	Operation at temperatures below -20°C or above +60°C may cause permanent damage.	Same as predicate
Storing and handling	Temperature: -20°C to +60°C (-4°F to +140°F)	Same as predicate
	Rel. humidity: < 90 %, non-condensing	Same as predicate
	Air pressure: 500 hPa to 1060 hPa	Same as predicate
Dimensions (HxWxD)	MADSEN OTOflex 100 (HxWxD): 20 cm x 4.9 cm x 7.8 cm (7.9” x 1.9” x 3.0”)	Stand-alone version: 190 mm x 248 mm x 261 mm (7.5” x 9.8” x 10.3”)
	Charger unit (HxWxD): 18 cm x 4.9 cm x 7.8 cm (6.9” x 1.9” x 3.0”)	PC-based version: 100 mm x 240 mm x 240 mm (3.9” x 9.4” x 9.4”)
		Quick Check probe: 28 mm x 22 mm x 100 mm (1.1” x 0.9” x 3.9”)
		Diagnostic probe: 10 mm x 10 mm x 25 mm (0.4” x 0.4” x 1.0”)
Weight	MADSEN OTOflex 100: 0.6 kg/1.3 lb	Stand-alone version: 2.65 kg/5.85 lb PC-based version: 1.65 kg/3.64 lb
	Charger unit: 0.23 kg/0.5 lb	N/A
Power supply	Battery types: Rechargeable (Ni-MH type) AA (R6) 1.2V, 4 pcs.	External power supply XP Power, type AFM60US24
	Battery supply voltage: Nom. 5 V, max. 6.4 V, min. 4.0 V (instrument power-off voltage)	Output: 24 V, 2.5 A
	Charger unit	N/A
	Type identification: Charger unit is type 1012 Charger from GN Otometrics A/S	N/A
	Power: 100 - 240 VAC ±10%, 50/60 Hz	Input: 100-240 V AC, 50-60 Hz, 1.5 A
	Power consumption < 10 VA	Power consumption < 60 VA
Miscellaneous	2cc coupler.	Same as predicate
	Clock and calendar.	Same as predicate
		Printer: Built-in printer. Prints 600 dot

Characteristic	K033645, OTOflex 100 Type 1012, GN Otometrics A/S.	K161707 Madsen Zodiac 1096 GN Otometrics A/S
		line/s on 112 mm paper width
Programming language	C++	C#
Calibration	Equipment should be calibrated regularly according to EN 61027 and ANSI S3.39	Same as predicate
Standards	Safety: ANSI/AAMI ES 60601-1 (2005), CAN/CSA -C22.2 NO 60601.1 (2008)	Same as predicate, but in latest edition
	MADSEN OTOflex 100: IEC 60601-1, Class II, Internal Powered, Type BF, IPX0	MADSEN Zodiac: EN 60601-1, Class II, externally powered, Type BF, IPX0
	Charger unit: EN 60601-1, Class II, IPX0	Power supply: Class I externally powered supply
	EMC: EN 60601-1-2, EN 300 328-2, EN 301 489-17	Same as predicate, but in latest edition
	Impedance/Admittance: EN 61027 Type 1, ANSI S3.39 Type 1	Same as predicate, but in latest edition
Command wheel	x	x
Tactile buttons	x	x
Hybrid (PC controlled and standalone)	x	x
Built-in 2cc test cavity	x	x
Replaceable test cavity	n/a	x
Diagnostic probe	x	x
Dedicated Screening probe	n/a	x
Two probes connected at once	n/a	x
Light indications on probe(s)	n/a	x
Control buttons on probe(s)	n/a	x
Contra phone	Insert type: Yes Supra-aural type: No	Insert type: Yes Supra-aural type: Optional
PC Connection	x	x
PC Connection Type	BlueTooth	USB
Controllable by PC	X	X
Internal Printer	NO	Yes

Characteristic	K033645, OTOflex 100 Type 1012, GN Otometrics A/S.	K161707 Madsen Zodiac 1096 GN Otometrics A/S
Photos		Stand Alone  PC Based 

7. Description of Non-clinical Testing: Testing consisted of mainly non-clinical performance testing of the device against the applicable parameters specified in the following standards:

	Standards No.	Standards Organization	Standards Title	Version
1	ANSI/AAMI ES60601-1 (2005) + AMD 1 (2012)	ANSI/AAMI	Medical Electrical Equipment -- Part 1: General Requirements for Basic Safety and Essential Performance	2012
	Standards No.	Standards Organization	Standards Title	Version
2	IEC 60601-1-2:2007	EN/IEC	Medical Electrical Equipment - Part 1-2: Collateral Standard Electromagnetic Compatibility Requirements and Tests	2007
	Standards No.	Standards Organization	Standards Title	Version
3	EN/IEC 60645-5 Types 1 and 2,	EN (Same as IEC)	Electroacoustics - Audiometric equipment - Part 5: Instruments for the measurement of aural acoustic impedance/admittance	2005
	Standards No.	Standards Organization	Standards Title	Version
4	ANSI S3.39 Types 1 and 2.	ANSI	American National Standard Specifications for Instruments to Measure Aural Acoustic Impedance and Admittance (Aural Acoustic Immittance)	1987 (R2012)

Additionally, biocompatibility of patient contact materials was evaluated according to ISO 10993 for irritation, sensitization, and cytotoxicity. Software validation and risk analysis was successfully conducted, and performance testing was done to assure compliance with our own product specifications. The specifications are detailed in the comparison table, above.

8. **Description of Clinical Testing:** Clinical testing was not required for a conclusion of substantial equivalence.

Conclusion: After analyzing bench testing, safety, EMC, applicable standards, and software validation testing we conclude that the Madsen Zodiac 1096 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.