K130937
JAN - 3 2014

510(k) Summary of Safety and Effectiveness

In accordance with the requirements of the Safe Medical Device Act, Hansaton Akustik GmbH herewith submits a Summary of Safety and Effectiveness.

Submitter Information:

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Date Prepared: January 03, 2014

Device(s) Identification:

Device Trade Name: WAVE 2G,
SOUL
Common Name: Tinnitus Maskers

Classification of the device:

Device Classification Name: Masker, Tinnitus
Product Code: **KLW**
Device Classification No.: Part 874.3400
Panel: Ear Nose & Throat
Regulatory Status: Class 2

Device Description:
The Hansaton Tinnitus Maskers are provided in two versions; the WAVE 2G, a noise generator intended to output noise for tinnitus habituation therapy and tinnitus masking therapy, and SOUL, a noise generator and hearing aid additionally providing amplification.
Both, the WAVE 2G and the SOUL systems are available as 'In The Ear' (ITE) and 'Behind The Ear' (BTE) versions.

Intended Use:
The Hansaton Tinnitus Maskers are air conduction broad band noise generators and hearing aids intended to output noise of sufficient intensity and bandwidth to be used for tinnitus habituation therapy and are suitable for tinnitus masking therapy. Optional, the Hansaton SOUL Tinnitus Maskers provide amplification, intended to be used by those individuals who experience tinnitus and desire amplification. Diagnosis and prescription of the tinnitus maskers must be performed by hearing health specialists (e.g., ENT specialists, audiologists, or hearing system professionals) who are experienced in tinnitus management.
The target population is primarily the adult population over 18 years of age. The instruments are not intended for pediatric use.

Predicate devices:

1.

Device Trade Name:	TCI Combi
Applicant:	Siemens Hearing Instruments
510(k) No.:	K003558

2.

Device Trade Name:	TCI
Applicant:	Siemens Hearing Instruments
510(k) No.:	K003559

3.

Device Trade Name:	Custom TCI Combi
Applicant:	Siemens Hearing Instruments
510(k) No.:	K011366

4.

Device Trade Name:	WIDEXLINK IN CLEAR SERIES HEARING AIDS
Applicant:	Office Research in Clinical Amplification
510(k) No.:	K101699

	Hansaton WAVE 2G	Hansaton SOUL	TCI Combi K003558	TCI K003559	Custom TCI Combi K011366	Widexlink in clear series hearing aids K101699
Intended Use	The Hansaton Tinnitus Maskers are air conduction broad band noise generators and hearing aids intended to output noise of sufficient intensity and bandwidth to be used for tinnitus habituation therapy and are suitable for tinnitus masking therapy. Diagnosis and prescription of the tinnitus maskers must be performed by hearing health specialists (e.g., ENT specialists, audiologists, or hearing system professionals) who are experienced in tinnitus management. The target population is primarily the adult population over 18 years of age. The instruments are not intended for pediatric use.	The Hansaton Tinnitus Maskers are air conduction broad band noise generators and hearing aids intended to output noise of sufficient intensity and bandwidth to be used for tinnitus habituation therapy and are suitable for tinnitus masking therapy. Optional, the Hansaton SOUL Tinnitus Maskers provide amplification, intended to be used by those individuals who experience tinnitus and desire amplification. Diagnosis and prescription of the tinnitus maskers must be performed by hearing health specialists (e.g., ENT specialists, audiologists, or hearing system professionals) who are experienced in tinnitus management. The target population is primarily the adult population over 18 years of age. The instruments are not intended for pediatric use.	Mask tinnitus as part of tinnitus management program Provide amplification for compensation of hearing loss	Mask tinnitus as part of tinnitus management program	Mask tinnitus as part of tinnitus management program Provide amplification for compensation of hearing loss	Mask tinnitus as part of tinnitus management program
Target population	Individuals who experience tinnitus. The target population is primarily the adult population over 18 years of age. The	Individuals who experience tinnitus and desire amplification. The target population is primarily the	Adults and children (≥ 5 years) with tinnitus and hearing loss that are participating in a tinnitus management program	Adults and children (≥ 5 years) with tinnitus that are participating in a tinnitus management program	Adults and children (≥ 5 years) with tinnitus that are participating in a tinnitus management program	Individuals with a full range of hearing loss severity (from slight (16 to 25 dB HL) to profound (90+ dB HL)) and all hearing loss

	Hansaton WAVE 2G	Hansaton SOUL	TCI Combi K003558	TCI K003559	Custom TCI Combi K011366	Widexlink in clear series hearing aids K101699
	instruments are not intended for pediatric use.	adult population over 18 years of age. The instruments are not intended for pediatric use.				configurations.
Circuit type	Digital	Digital	Digital	Digital	Digital	Digital
Programmable	Yes	Yes	Yes	Yes	Yes	Yes
Multiple programs/ memories	Yes (except Cymba)	Yes (except Cymba)	Yes	No	Yes	Yes
Available noises	Four	Four	One	Four	One	n/a
Volume control	Yes	Yes	Yes	Yes	Yes	Yes
Number of channels	Eight	(G/AGC) Business: 12/12 Economy: 8/4	Four	n/a	n/a	n/a
Physical description	Available as standard behind-the-ear (X-Mini and Slim) and in-the-ear solutions (Mini Canal and Cymba); Mini Canal is custom made	Available as standard behind-the-ear (X-Mini and Slim) and in-the-ear solutions (Mini Canal and Cymba); Mini Canal is custom made	Standard behind-the-ear instrument housing	Standard behind-the-ear instrument housing	Custom product, available as in-the-ear, half shell, and in-the-canal shell styles	n/a
RMS output characteristics (Noiser)	Mini Canal 80 dB Slim 80/90 dB X-Mini (S-receiver) 70 dB X- Mini (M-receiver) 80 dB	Mini Canal: 75 dB Slim: 75/85 dB (Mini tube/ earhook) X-Mini (S-receiver): 65 dB X-Mini (M-receiver): 75 dB X-Mini (P-receiver) 85 dB	102 dB Broadband noise	White noise 71 dB SPL Pink noise 69 dB SPL Speech noise 69 dB SPL High-tone noise 76 dB SPL	ITE: 89 dB Broadband noise In-the-canal and half shell: 84 dB Broadband noise	n/a
RMS output characteristics (Hearing aid amplifier)	n/a	(ANSI S3.22-2003) HF-Average OSPL 90 Mini Canal: 111 dB	105 dB HF-Average OSPL 90 (ANSI S3.22-1996)	n/a	ITE: 105 dB HF-Average OSPL 90 (ANSI S3.22-1996) (110/40/03 matrix)	n/a

	Hansaton WAVE 2G	Hansaton SOUL	TCI Combi K003558	TCI K003559	Custom TCI Combi K011366	Widexlink in clear series hearing aids K101699
		Slim: 116 dB X-Mini (S-receiver): 101 dB X-Mini (M-receiver): 114 dB X-Mini (P-receiver) 116 dB			In-the-canal and half shell: 107 dB HF-Average OSPL 90 (ANSI S3.22-1996) (110/35/03 matrix)	
Volume control range	Programmable: OFF, 8 dB, 16 dB, 32 dB	Programmable: OFF, 8 dB, 16 dB, 32 dB	Programmable: OFF, 8 dB, 16 dB, 32 dB	Programmable: OFF, 8 dB, 16 dB, 32 dB	Programmable: OFF, 8 dB, 16 dB, 32 dB	n/a
Wireless communication of pair of hearing aids or device accessories	No	Yes	No	No	No	Yes

The Hansaton WAVE 2G and SOUL Tinnitus Maskers are considered substantial equivalent to the Siemens TCI Combi (K003558), Siemens TCI (K003559), Siemens Custom TCI Combi (K011366), and Office Research in Clinical Amplification's WIDEXLINK (K101699). There is no significant difference in intended use or technology.

Summary of performance testing:
The Hansaton WAVE 2G and SOUL tinnitus maskers have been developed and tested in accordance with hearing aids specific standard IEC 60118 series.

- IEC 60118-0: Hearing aids – Measurement of electroacoustical characteristics
- IEC 60118-1: Hearing aids – Hearing aids with induction pick-up coil input
- IEC 60118-2: Hearing aids –Hearing aids with automatic gain control circuits
- IEC 60118-6: Hearing aids –Characteristics of electrical input circuits for hearing aids
- IEC 60118-13: Hearing aids –Electromagnetic compatibility

All patient contacting materials have been evaluated in terms of biocompatibility in accordance with the ISO 10993 standard series.

Additionally a speech test was performed in accordance with the Nordic Requirements 7th edition appendix A.

Conclusion:
Hansaton Akustik GmbH believes that the Hansaton Tinnitus Maskers WAVE 2G and SOUL are substantially equivalent to the currently legally marketed devices. They do not introduce new indications for use, have the same technological characteristics and do not introduce new potential hazards or safety risks.

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

January 3, 2014

Hansaton Akustik GmbH
c/o Mr. Nick Burmester
Regulatory Affairs & Project Manager, Prosystem AG
Beim Strohhause 17
Hamburg, Germany 20097

Re: K130937
Trade/Device Name: WAVE 2G, SOUL
Regulation Number: 21 CFR 874.3400
Regulation Name: Tinnitus Masker
Regulatory Class: Class II
Product Code: KLW
Dated: November 18, 2013
Received: December 2, 2013

Dear Mr. Burmester:

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 contact 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. 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,

Bradley S. Cunningham -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

Indications for Use

510(k) number (if known): K130937

Device Name: WAVE 2G, SOUL Tinnitus Masker

Indications for Use: The Hansaton Tinnitus Maskers are air conduction broad band noise generators and hearing aids intended to output noise of sufficient intensity and bandwidth to be used for tinnitus habituation therapy and are suitable for tinnitus masking therapy. Optional, the Hansaton SOUL Tinnitus Maskers provide amplification, intended to be used by those individuals who experience tinnitus and desire amplification. Diagnosis and prescription of the tinnitus maskers must be performed by hearing health specialists (e.g., ENT specialists, audiologists, or hearing system professionals) who are experienced in tinnitus management.

The target population is primarily the adult population over 18 years of age. The instruments are not intended for pediatric use.

Prescription Use___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Srinivas Nandkumar -S