K110973

MAY - 5 2011

510(K) Summary for the Widex *IE-Zen* Program in the CLEAR Series Hearing Aids

Submission Date	**April 4, 2011**
Applicant	**Widex USA** **35-53, 24th street** **Long Island City, NY 11106** **Phone: 800-221-0188**
Contact Person	**Francis Kuk, Ph.D.** **2300 Cabot Drive, Suite 415** **Lisle, IL 60532** **630-245-0025** **Email: Fkuk@widexusa.com** **Fkuk@aol.com**
Trade or Proprietary Name	**IE-Zen (in CLEAR series hearing aid)**
Device Common Name/ Classification name	**Tinnitus Masker**
Product Code	**KLW**
Classification of Device	**Class II for wireless hearing aids** **Class II for tinnitus masker**
Establishment Registration Number	**2430101**
Address of Manufacturing Site	**Widex A/S** **Nymoellevej 6** **DK-3540 Lynge** **Denmark**
Reason for Submission	**Inclusion of IE-Zen in CLEAR series hearing aids**
Marketed Devices with Substantial Equivalence	**K101699 for WidexLink in CLEAR440** **K080955 Zen program in Widex mind440**

510 K Executive Summary

Description of Device

The CLEAR series hearing aids (including CLEAR440, CLEAR330, CLEAR220 and super-power SUPER440 and SUPER220 - also privately labeled as REVIVE700, REVIVE640, REVIVE630, REVIVE707 and REVIVE637) are digital wireless air conduction hearing aids all using the WidexLink radio. The different series represent different price points for the CLEAR hearing aids (see discussion of difference in application). The WidexLink is a low power proprietary radio, which enables communication between hearing aids and from other peripheral units. We have two units which can communicate with the CLEAR hearing aids: a simple remote control (RC-DEX) which can change volume and program in the hearing aid and a programming unit (TM-DEX) which is used in combination with a universal programming interface - nEARcom/NoahLink programming system. A detailed description of the WidexLink platform is available in the 510K application (K101699).

The added feature to the approved CLEAR440 hearing aid is the optional inter-ear Zen (IE-Zen) feature. Wireless is used in the IE-Zen to identify if the Zen program is used in a monaural mode or binaural mode. The IE-Zen is a tool that generates and delivers a relaxing sound background. It may also be used as a sound source to distract and/or mask tinnitus in tinnitus sufferers. A broadband noise and 5 melodic tone patterns that are generated using fractal mathematics can be selected as Zen programs. The clinician can adjust the characteristics (intensity, pitch and tempo) of each program and the patient can retrieve up to 3 programs with the touch of a program button. The IE-Zen can be used with or without amplification.

Indications for use

The IE-Zen program is intended to provide a relaxing sound background for adults (21 years and older) who desire to listen to such a background in quiet. It may be used as a sound therapy tool in a tinnitus treatment program that is programmed by a licensed hearing healthcare professional (audiologists, hearing aid specialists, otolaryngologists) who is trained in tinnitus management.

Technological comparison to predicate devices

The WidexLink wireless platform used in the CLEAR440 is identical to the WidexLink platform used in the CLEAR440, of which a 510K has been granted (K101699).

The IE-Zen is substantially equivalent to the original Zen program (K080955) in rationale, mechanism, and applications. Whereas the original Zen program generates the full set of tones regardless of how the mind440 is worn (either binaurally or monaurally), the IE-Zen in the CLEAR only generates a half set of tones in each CLEAR hearing aid

of a binaural pair, and the full-set of tones if the CLEAR is worn monaurally. This is possible in the CLEAR because of inter-ear wireless communication between hearing aids. When a partner hearing aid (belonging to the CLEAR family) is detected, the IE-Zen program registers binaural hearing aid use and sets the IE-Zen in each CLEAR hearing aid to half the total tones generated.

Risks to health

There is no more risk to the use of the IE-Zen program than the use of conventional hearing aids and/or tinnitus masker. There is also no known risk associated with the use of wireless hearing aids (WidexLink) because of its low output level and magnetic field strengths (K101699). Appropriate labeling is included to ensure proper use of the device.

Conclusion from preclinical tests and clinical studies

Acoustic measurements of the IE-Zen tones showed that the overall levels of the IE-Zen and Zen tones were similar. As expected, the spectra of the IE-Zen tones were different from the Zen tones between binaural and monaural presentations. A study on the acceptability of the IE-Zen tones to hearing impaired people showed that the majority of listeners (80%) rated the IE-Zen tones as "somewhat relaxing" or ""very relaxing." The preference for the IE-Zen tones was similar to that for the Zen tones. An independent study conducted at UCSF demonstrated that the Zen tones were effective in reducing tinnitus severity for some tinnitus sufferers. The IE-Zen program is expected to be just as effective as the predicate device (K080955) while the safety of the hearing aid is unaltered.

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

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Widex USA
C/O Francis Kuk, Ph.D.
2300 Cabot Drive, Suite 415
Lisle, IL 60532

Re: K110973
Trade/Device Name: IE-Zen
Regulation Number: 21 CFR 874.3400
Regulation Name: Tinnitus masker
Regulatory Class: Class II
Product Code: KLW
Dated: April 4, 2011
Received: April 6, 2011

Dear Dr. Kuk:

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

K110973

Indications for Use

510(k) Number (if known): K110973

Device Name: IE-Zen program (in CLEAR series hearing aids including CLEAR Super)

Indications for Use:

The IE-Zen program is intended to provide a relaxing sound background for adults (21 years and older) who desire to listen to such a background in quiet. It may be used as a sound therapy tool in a tinnitus treatment program that is programmed by a licensed hearing healthcare professional (audiologists, hearing aid specialists, otolaryngologists) who is trained in tinnitus management.

Intended Use

The IE-Zen program is intended to be used in quiet where hearing everyday sounds is not critical.

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 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 K110973