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

Widex Hearing Aid Company
c/o Francis Kuk, Ph.D.
2300 Cabot Drive, Suite 415
Lisle, IL 60532

MAR 3 1 2011

Re: K101699
C4-PA model (Clear 440 Passion) hearing aid of the CLEAR 440 series
Evaluation of Automatic Class III Designation
Regulation Number: 21 CFR 874.3305
Classification: II
Product Code: OSM

Dear Dr. Kuk:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your Evaluation of Automatic Class III Designation Petition (de novo) for classification of the C4-PA model (Clear 440 Passion) hearing aid of the CLEAR440 series of hearing aids. The C4-PA hearing aid is a digital wireless air-conduction hearing aid that is indicated to amplify sounds for individuals with a hearing impairment and is subject to labeling and conditions for sale requirements under 21 CFR Part 801.420 and 801.421. FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class II. This order, therefore, classifies the C4-PA model hearing aid of the CLEAR 440 series, and substantially equivalent devices of this generic type into class II under the generic name, wireless air-conduction hearing aid. This order also identifies the special controls applicable to this class II device.

FDA identifies this generic type of device as:

> A wireless air-conduction hearing aid is a wearable sound-amplifying device, intended to compensate for impaired hearing, that incorporates wireless technology in its programming or use.

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(1)) (the act), devices that were not in commercial distribution prior to May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976 (the amendments)), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act (21 U.S.C. 360c(i)), to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket

notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and Part 807 of the FDA regulations (21 CFR 807).

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) for a device may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1), request FDA to classify the device under the criteria set forth in section 513(a)(1). FDA shall, within 60 days of receiving such a request classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register classifying the device type.

In accordance with section 513(f)(1) of the act, FDA issued an order on September 13, 2010 automatically classifying the CLEAR 440 series of hearing aids in class III, because it was not within a type of device which was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, nor which was subsequently reclassified into class I or class II. On October 13, 2010, FDA filed your petition requesting classification of the CLEAR 440 series of hearing aids into class I or class II. The petition was submitted under section 513(f)(2) of the act. In order to classify the CLEAR 440 series of hearing aids into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

After review of the information submitted in the petition, together with the information you provided in interactive review, FDA has determined that the C4-PA model (Clear 440 passion) hearing aid indicated for the amplification of sounds for individuals with a hearing impairment can be classified in class II with the establishment of special controls. FDA believes that class II special controls provide reasonable assurance of the safety and effectiveness of the device type.

Potential Risks

Identified Risk	**Recommended Mitigation Measures**
Degradations in device function due to electromagnetic interference (EMI)	Electromagnetic compatibility (EMC) testing; Labeling
Degradations in device function due to wireless technology disruption such as slow-down, lost or corrupted information, security issues including potential cross-talk or control by other users with a similar medical device	Wireless technology design, description, and testing; Performance testing; Labeling
Exposure to non-ionizing radiation emitted by wireless technology can potentially induce tissue heating	Wireless technology design, description, analysis, and testing; Labeling

In addition to the general controls of the act, the CLEAR 440 Series is subject to the following special controls: 1) Appropriate analysis/testing should validate EMC and safety of exposure to non-ionizing radiation; 2) Design, description, and performance data should validate wireless technology functions; and 3) Labeling should specify appropriate instructions, warnings, and information relating to EMC and wireless technology and human exposure to non-ionizing radiation. Section 510(m) of the act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is exempt from the premarket notification requirements of the act. Thus, persons who intend to market this device type need not submit to FDA a premarket notification submission containing information on the wireless air-conduction hearing aid they intend to market prior to marketing the device and receive clearance to market from FDA subject to the limitations on exemptions in 874.9.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the de novo, subject to the general control provisions of the act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact (b)(6) at (b)(6).

Sincerely yours,

Jonette Foy, Ph.D.
Acting Deputy Director
for Science and Regulatory Policy
Office of Device Evaluation
Center for Devices and Radiological Health