SUMMARY REVIEW MEMO

DATE: MARCH 31, 2011

FROM: (b)(6), DONED/ENTB

SUBJECT: EVALUATION OF AUTOMATIC CLASS III DESIGNATION PETITION # K101699 AND C4-PA WIRELESS AIR-CONDUCTION HEARING AID

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TO: THE RECORD

REGULATORY INFORMATION

REGULATION NUMBER: 874.3305

FDA identifies this generic type of device within 21 CFR 874.3305 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.

CLASSIFICATION: II (EXEMPT FROM PREMARKET NOTIFICATION SUBJECT TO 21 CFR 874.9)

PRODUCT CODE: OSM

BACKGROUND

This premarket submission was found not substantially equivalent (NSE) on September 13, 2010 due to the lack of a predicate device with the same technological characteristics.

The petitioner is requesting an evaluation of Automatic Class III Designation for the C4-PA hearing aids with WidexLink wireless technology. The petitioner recommends that their device be reclassified into Class I or Class II. Additional hearing aid models with wireless technology will require similar bench testing as outlined in this submission.

REVIEW TEAM

- Lead & Software – (b)(6)
- EMC and Wireless – (b)(6)
- Audiology – (b)(6)
- Audiology – (b)(6)
- Impact of electromagnetic emissions on health – (b)(6)
- Biocompatibility – (b)(6)

INDICATIONS FOR USE

The CLEAR440 - PASSION (or C4-PA) hearing aid is a digital wireless air conduction hearing aid that amplifies sounds for individuals with a hearing impairment. The device is indicated for 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 configurations. The device is to be programmed by hearing healthcare professionals (audiologists, hearing aid specialists, otolaryngologists) who are trained in hearing (re)habilitation.

DEVICE DESCRIPTION

The C4-PA is a digital air-conduction hearing aid that uses WidexLink, a wireless radio technology to enable communication between a pair of hearing aids and/or between the hearing aid(s) and certain device system accessories. Accessories for WidexLink include the optional remote control (RC-DEX) (see Figure 1) and the Widex-specific programming module (TM-DEX) (see Figure 2).

Figure 1. Pair of C4-PA hearing aids and RC-DEX remote control. This represents a daily use scenario.

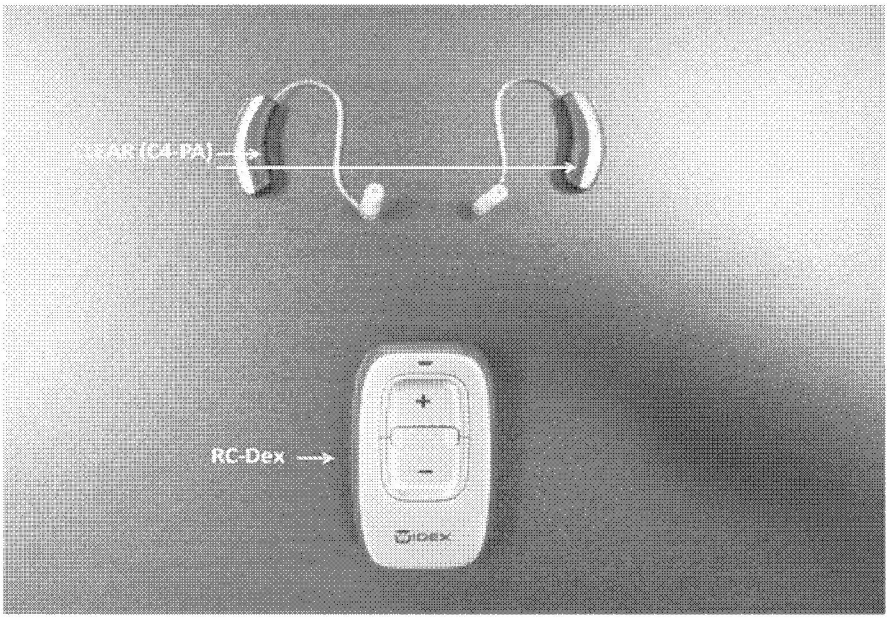
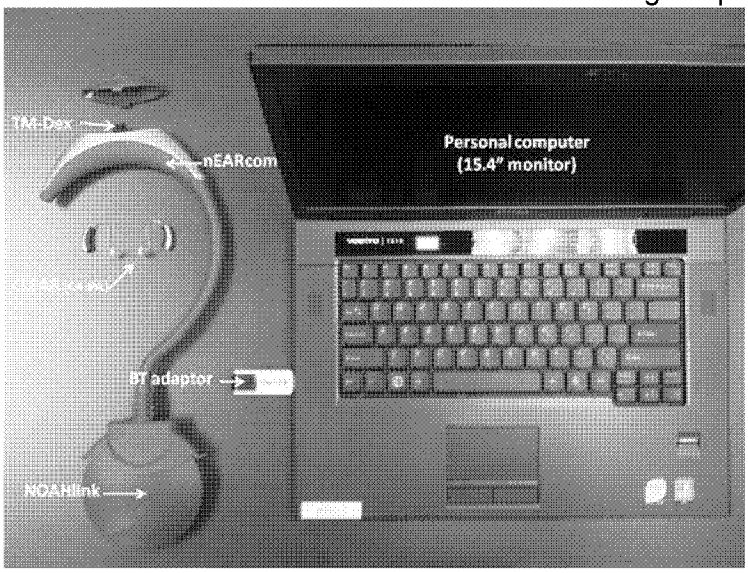


Figure 2. Arrangement of components used during programming of C4-PA hearing aid(s). The nEARcom is worn around the wearer's neck during the programming session.



The RC-DEX is used by the wearer to change volume and program settings on the hearing aid(s). The TM-DEX is used during programming to fit the hearing aids. The fitting software (Compass) runs on the programming personal computer (PC). In addition, a universal programming interface – nEARcom with Bluetooth (BT)-enabled NOAHlink (non-specific to Widex), is also required to program the C4-PA hearing aid(s).

Technical description of WidexLink and the C4-PA device system

WidexLink is a low power, short-range, proprietary radio which enables communication between the C4-PA hearing aid(s) and certain peripheral units (RC-DEX and TM-DEX). Table 1 contains specifications for the wireless technology, including WidexLink, of appropriate components of the device system. WidexLink is used in two configurations/modes:

1. **Programming mode** – In this mode, the C4-PA hearing aid(s) are programmed by the fitting clinician. Programming is conducted wirelessly (without cables) through the TM-DEX, which is used in combination with the NOAHlink/ nEARcom (see Figure 2 above). During programming, the TM-DEX provides a two-way link for exchange of data between the PC and the hearing aids (semi-duplex) via NOAHlink. The transmission of information through the various programming components occurs as follows:

    - Compass fitting software - The source code for the applied programming unit is compiled into the fitting software called Compass.
    - NOAHlink driver - NOAHlink is a wireless converter between the PC interface and various electrical communication devices. To use NOAHlink, the user logs in via a basic NOAHlink driver object within the PC. Only one user is allowed at any one time. Once logged in, the user is assigned a randomized

handle (8 bits) that allows access the desired protocol (Inter-Integrated Circuit [I2C] for the C4-PA hearing aid). Login to a protocol object automatically makes the NOAHlink driver download a binary protocol for the NOAHlink hardware – this protocol is used to manage the NOAHlink hardware during communication.

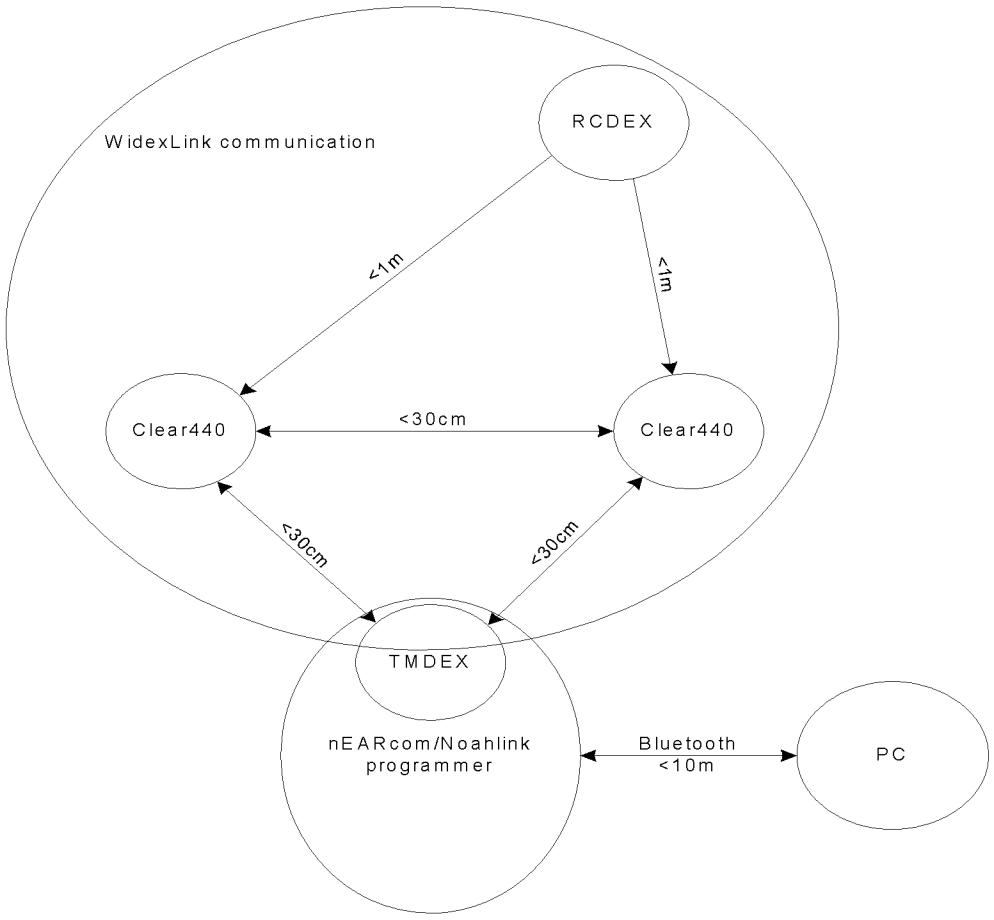
- Bluetooth (BT) connection - Data from the Compass fitting software are sent to NOAHlink via the NOAHlink driver using a wireless Bluetooth (BT) connection operating in the 2.4 GHz frequency band. NOAHlink uses a Class II Bluetooth which includes only one Bluetooth profile (SPP) for login. Once the NOAHlink driver is logged in via the PC's BT module, the user will only be allowed to discover, but not log into NOAHlink from another BT module in the environment. Specifications for the BT connectivity used in NOAHlink follow:
    - BT version 2.0
    - BT Profile SPP (Serial Port Profile)
    - Fixed passkey (b)(4) (due to Windows XP BT Stack that cannot run in un-secure mode)
- NOAHlink - The wireless converter (NOAHlink) receives/transmits data from/to the PC (via BT). NOAHlink transmits/receives data from the C4-PA hearing aid(s)) via the I2C protocol. For communication with the C4-PA hearing aid(s), data are wirelessly sent via the nEARcom/ TM-DEX wireless programming/ fitting module.
- nEARcom - The nEARcom is the physical housing that houses and allows the choice of the desired wireless fitting modules. One of five fitting modules can be inserted in the nEARcom. TM-DEX is the name of the fitting module for the C4-PA hearing aid(s). Once a fitting module is enabled, nEARcom becomes a passive element in communication.
- TM-DEX - Depending on the I2C address and destination Media Access Control (MAC) address, the TM-DEX routes commands from the fitting software to the relevant hardware. Some commands target the TM-DEX module while others are routed across the wireless interface via WidexLink to the C4-PA hearing aid(s). A carrier frequency at 10.6 MHz is used for the WidexLink digital transmission between the TM-DEX and the hearing aid(s) (described further below and in Table 1).
- C4-PA hearing aid – the C4-PA hearing aid(s) receive programming/fitting data from the TM-DEX wirelessly one hearing aid at a time. To communicate with a hearing aid, the TM-DEX needs to know the MAC address of or be recognized by the hearing aid. The C4-PA hearing aid is powered by a standard 1.4 V Zn-Air hearing aid battery.

2. **Daily use mode** – This is the mode in which the wearers use the C4-PA hearing aid(s), in either a monaural or binaural fashion. Figure 1 shows the components of the daily use configuration. When a pair of C4-PA hearing aids is used binaurally, data is transmitted between the hearing aids (referred to as inter-ear communication) in a semi-duplex manner. The hearing aids update parameter settings 20 times per second automatically and continuously. When the C4-PA hearing aid is used in a monaural manner, no automatic update of hearing aid

settings will be available. In addition, the wearer can choose to use the external remote control (RC-DEX) to make volume and program changes on the hearing aid either monaurally or binaurally. RC-DEX transmits data to the hearing aid(s) in a one-way (or simplex) manner. A carrier frequency at 10.6 MHz is used for the WidexLink digital transmission between the RC-DEX and the hearing aid(s)

Range - Figure 3 (below) shows the range of wireless communication among the C4-PA hearing aids and other components of the device system. The range is within 30 cm between the pair of hearing aids, less than one meter between the hearing aid(s) and the RC-DEX, and less than 30 cm between the TM-DEX and the hearing aid(s). All communication inside the large blue circle is accomplished wirelessly through the short-range WidexLink radio. The RC-DEX and C4-PA hearing aid(s) lie completely inside this circle, as they contain only the WidexLink wireless radio. The BT connection between the personal computer and NOAHlink used during hearing-aid fitting has a transmission range of less than 10 meters (Power Class II).

Figure 3: Relationship and range of transmission of the various WidexLink and programming components.



WidexLink specifications - WidexLink is the proprietary radio used in the C4-PA hearing aid(s), RC-DEX, and TM-DEX. WidexLink is an inductive short-range device (SRD) using an inductive ferrite coil antenna and Frequency Shift Keying (FSK)

modulation with a carrier frequency at 10.6 MHz and a bandwidth of 660 kHz (-15 dB). The radio chip is identical in all units (C4-PA, TM-DEX, RC-DEX) although the exact configuration is component specific. The transmitter produces a modulated magnetic field from the alternating current that passes through the antenna coils, and the RF receiver picks up the modulated magnetic field and converts this to a voltage which is fed to the radio receiver. WidexLink is a single channel digital radio with a raw channel capacity of 212 kbit/s. The hearing aids and the TM-DEX use a semi-duplex data flow (meaning data flow in both directions, but not simultaneously) while the RC-DEX uses a simplex or one-way data flow. The RC-DEX is available for C4-PA users to control the program and volume settings on the hearing aids, and the TM-DEX is only available to the hearing aid dispenser/ professional for programming the C4-PA hearing aid(s). All components containing WidexLink (C4-PA, TM-DEX, RC-DEX) use a Random Access protocol with no collision avoidance when transmitting data. All configurations of radio modules are set by either Widex or by the Compass fitting software during fitting; the user cannot configure the radio.

NOAHlink BT specifications - NOAHlink communicates with the programming PC through a Bluetooth radio (BT version 2.0; Serial Port Profile (SPP); fixed Pass Key for security) which uses a 2.4 GHz carrier with 79 channels and a bandwidth of 1 MHz.

Technical details of the WidexLink and BT radios used in the C4-PA device system are summarized in Table 1:

Table 1. Technical specifications of radios in the C4-PA device system. *Bluetooth specification v2.0 + EDR published by the Bluetooth Special Interest Group (SIG); Bluetooth Identifier: B01837; Reference number of Qualified Product Notice (QPN): NOAHlinkV1.2_412832_QPN_E1. **EIRP: Equivalent isotropically radiated power. ***FHSS: Frequency-hopping spread spectrum. GFSK: Gaussian Frequency-Shift Keying; π/4 DPSK: Differential Phase-shift keying with 4 constellation points rotated 45°; 8 DPSK: Differential Phase-shift keying with 8 constellation points.

	C4-PA hearing aid(s)	**RC-DEX**	**TM-DEX**	**Bluetooth* - NOAHlink**
Antenna type	Inductive antenna	Inductive antenna	Inductive antenna	Embedded ceramic antenna
Antenna dimensions	Ø1.8 mm, L – 4.85 mm	Ø8 mm, L – 20 mm	Ø6 mm, L – 8 mm	NA
Modulation	FSK	FSK	FSK	FHSS/GFSK, π/4 DPSK, 8 DPSK***
Magnetic Field Strength (at 10 m distance)	-54 dBμA/m	-13 dBμA/m	-26 dBμA/m	NA
Output power (EIRP)**	29 pW	21 nW	1.2 nW	+4 dB re 1 mW maximum (Power class 2)
Range	< 1 m remote unit to hearing aid < 30 cm between hearing aids or hearing aid to TM-DEX	< 1 m remote unit to hearing aid	< 30 cm between hearing aid and TM-DEX	< 10 m between PC and NOAHlink
Center frequency	10.6 MHz	10.6 MHz	10.6 MHz	2.4 GHz
Channel	Single channel radio	Single channel radio	Single channel radio	5 logical channels
Bandwidth	660 kHz (-15 dB)	660 kHz (-15 dB)	660 kHz (-15 dB)	1 MHz
Data-rate	212 kbit/second (raw channel capacity)	212 kbit/second (raw channel capacity)	212 kbit/second (raw channel capacity)	2.1 Mbps
Data flow	Simplex or semi-duplex capability	Simplex capability	Simplex or semi-duplex capability	Time division duplex (TDD)
Protocol	Random Access – no collision avoidance	Random Access – no collision avoidance	Random Access – no collision avoidance	Packet-based protocol, time divided; secure Serial Port Profile (SPP)

FDA Review Note: *The information in Table 1 is included in the user manuals for the C4-PA hearing aids, the RC-DEX, and the nEARcom. We agree that this information should be included in the labeling to convey details to both users and clinicians about the WidexLink and BT wireless technologies incorporated in the device system.*

Audiological features realized by WidexLink

The discussion above provides a technical description of the WidexLink and BT codecs used in the C4-PA hearing aids and the components of the device system. This section describes the audiological features of the C4-PA hearing aids, focusing on those features enabled by WidexLink wireless technology. It is noted that each of the following features are available only for binaurally worn C4-PA hearing aids. These features fall under the class *Inter-ear communciation between hearing aids.* Inter-ear communication enables the wireless exchange of data between two hearing aids so that each aid can evaluate the information from the other. The goal is for the two hearing aids to work in concert. Inter-ear communication *is on by default and can only be deactivated by the clinician during programming*. Inter-ear features include:

- *Synchronization of volume control settings between hearing aids:* The volume in both hearing aids will change when the volume is adjusted on only one side to improve usability for the user.

- *Synchronization of listening programs between hearing aids:* The same listening program can be set on both sides when changed by the user on only one side. The "compound program" option permits customized sets of listening programs for the two ears if different listening programs are desired for each side.

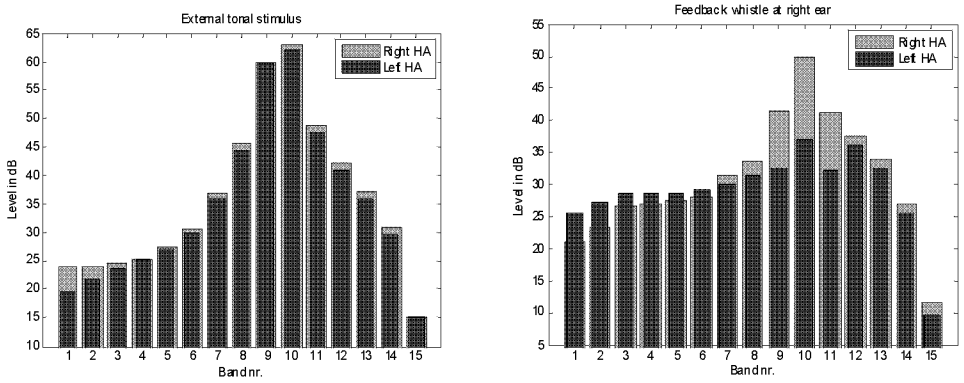
- *Surveillance of partner hearing aid:* The hearing aid(s) signal an alarm ("partner check") when a hearing aid fails to receive synchronization data from the partner hearing aid. This may be the result of an expired battery or if the maximum transmission distance is exceeded. In rare instances, a much stronger electromagnetic source nearby may activate this alert. This feature ensures the quality of the wireless service and serves as an early warning to the wearer of service interruption.

- *Coordination of compression (Inter-ear (IE) compression):* Hearing aid compression compensates for the reduced dynamic range of the hearing impaired ear so that soft sounds are audible and loud sounds are comfortable. When sounds are presented to one side (thus creating a head shadow effect), this compressive action could disrupt the interaural level difference (ILD) cue in a fast acting compression hearing aid. By sharing information of the input levels between the two ears wirelessly and having the higher input level determine the gain at each ear, the unaided ILD is preserved. The petitioner provides clinical data which suggests that that IE compression preserves the ILD cue for users

with both symmetrical and asymmetrical hearing losses, without resulting in a poorer speech perception when speech is introduced to one side (clinical data are summarized later in this memo). In addition, the petitioner suggests the possibility that coordination of compression may improve speech understanding in noise, although no clinical data are provided and no related claims are made.

- *Identification of feedback:* An important objective of an active feedback cancellation system is to accurately identify feedback and not a signal of interest (such as a musical tone). Otherwise, signals of interest may be incorrectly identified and cancelled. Moreover, artifacts and poor sound quality can result. Inter-ear communication between a pair of C4-PA hearing aids may improve the identification of feedback. By comparing the audio inputs to both hearing aids, the likelihood of identifying feedback occurring asymmetrically (i.e., on one side) may be improved. For example, an acoustic signal should result in a microphone-transduced signal that is relatively similar in spectral shape across both hearing aids (Figure 4, left panel). In contrast, a feedback signal will likely result in spectral asymmetries (right panel). Thus, by comparing spectra of the transduced signals across hearing aids, the accuracy of feedback identification may be improved.

Figure 4. Comparing feedback identification for an acoustic signal (left panel) and true feedback (right panel). The left panel plots the spectra of a 2500 Hz tone (presented from the front) at the microphone of the left (blue) and right (red) hearing aids. The similar input spectra across the frequency bands of the two hearing aids suggest that the input is likely an external acoustic signal (i.e., not feedback). The right panel shows a large increase in the magnitude of the 2500-Hz frequency band (band #10) of the right hearing aid. This suggests that the right hearing aid is likely experiencing feedback.



- *Coordination of noise reduction modes (Inter-ear Speech Enhancer):* C4-PA hearing aids share the results of the acoustic analysis between partner aids in an attempt to identify the side with a dominant speech input or a dominant noise. This is the case when a talker is to one side of the hearing aid wearer in a noisy background. Once the two sides have been determined, the hearing aid on the speech-determined side is set to Speech Enhancer mode in an attempt to maximize audibility through the optimization of the speech intelligibility index (SII). The other hearing aid is set to maximize comfort without affecting the SII

through uniform gain reduction. The goal is to differentially emphasize the speech frequencies on the side of the talker and increase listener comfort on the other side.

FDA Review Note: *The features listed above are described in the Compass software user manual. It is appropriate that this information is included in the user labeling to describe audiological features of WidexLink to clinicians who can share this information with patients. Since the petitioner did not make any specific performance related claims for these features in their labeling, clinical performance data supporting feature-related claims are not necessary. However, if the petitioner wishes to make performance related claims in the future, clinical testing to support those claims would be necessary.*

Performance and Quality of Service

WidexLink technology enables wireless communication between the two partners of a pair of C4-PA hearing aids (when used binaurally) and the hearing aid(s) and the TM-DEX and RC-DEX external devices (when used monaurally or binaurally). BT wireless technology enables communication between the programming PC and the NOAHlink. The requirements for quality of service (QoS) vary among the various components and their intended user scenarios. QoS is defined as an agreed-upon level of performance in a data communications system or other service, typically encompassing multiple performance parameters, such as reliability of data transmission, transfer rate, error rate, and mechanisms and priority levels for time-critical signals.The following paragraphs outline the design, specifications, and recommendations for QoS relating to the C4-PA device system.

Programming **–** This is the necessary first step conducted by dispensers who are trained in the operation of the devices and the use of the fitting software.

Transmission Flow – The wireless transmission flow during programming originates from the Compass fitting software run on a personal computer (PC). Commands pass through the NOAHlink driver, BT (Bluetooth) stack, NOAHlink hardware, nEARcom, Widex fitting module (i.e., TM-DEX) before reaching the C4-PA hearing aids. Communication occurs both ways (semi-duplex) during programming because confirmation is always required.

Quality of service design requirements – The wireless transmission of programming data must be safe, secure, and efficient. Potential sources of interference from nearby RF sources that use either the 2.4 GHz carrier frequency or a 10.6 MHz carrier frequency that may interfere with either BT or WidexLink must be anticipated. Given that programming is most likely done in a dispenser's office, interference from Wi-Fi and/or WLAN and other BT enabled accessories is possible. Potential interference cases have been tested and evaluated by the petitioner and are described below in the bench testing section.

Design considerations to ensure quality of services – The BT connection and the WidexLink connection between the TM-DEX and hearing aid(s) are considered separately:

1. Data exchange between PC and NOAHlink (BT connection)
The security of data exchange is ensured by several layers of protection. The fitting software is ready-compiled and cannot be modified by anyone but its developers. It can be executed only by authorized individuals who must log in to use the program. The process requires authorization and only one person may log in at a time. A pass key is required to ensure a secure BT connection. Any unauthorized use of the fitting software or interference with the connection will be detected and an error message will be displayed.

The security and accuracy of the data transmission is further enhanced by the following measures. The fitting software validates the status of all commands sent to the hearing aids in order to verify the proper execution of the command. The Received Signal Strength Indication (RSSI) is used to adjust the transmit power to maintain an optimal signal-to-noise ratio (SNR). Channel hopping is also used to locate the BT channel with the least amount of interference. In the event of interference from other nearby high-intensity BT devices, the speed of programming could potentially slow down. This may eventually lead to the display of "communication error" on the computer screen and cessation of programming. No data on the C4-PA hearing aids will be affected in such a case. A new login to the NOAHlink, which forces a complete reload of hearing aid data to the fitting software, will be needed to restart programming.

2. Data exchange between TM-DEX and C4-PA hearing aids
Security of data exchange between the TM-Dex and the C4-PA hearing aids is ensured with the use of a dedicated MAC address for the TM-Dex. A transmission latency of (b)(4) is hard-coded in the chip design and cannot be changed by the user. As the transmission is semi-duplex, the direction of the transmission changes every time when it switches from receive to transmit mode (RX to TX, and vice versa) which takes about (b)(4). Along with the (b)(4) for transmission in one direction (or (b)(4) in both directions), a total data turnaround time of (b)(4) is expected. Neither packet buffering nor priority system are used because only one user is allowed. Thus, there is no jitter on packet transmission. Data are not sensitive to clock jitters as the transmitter clock is extracted in the receiver clock data recovery circuit. To ensure the accuracy of the transmission, the transmitter expects acknowledgement from the receiver with every data package sent. All the data are combined with Cyclic Redundancy Check (CRC) to validate the data. A Bit Error Rate (BER)

better than 10^{-3} is ensured by the link, which contributes to the reliable transmission of data.

Recognizing and handling possible electromagnetic interference during programming with WidexLink wireless technology (for dispensers only)

Under optimal conditions (office type setting with other devices within transmission range, but no strong interference at similar carrier frequencies), the WidexLink and the BT-NOAHlink demonstrate secure and robust transmission. However, excessive interference from other devices nearby could slow down the transmission or even cause communication to fail.

To ensure successful data transmission, Compass (fitting software) expects an acknowledgement from the hearing aid (via the BT-NOAHlink-nEARcom/TM-DEX system chain) with every data package sent. If this acknowledgement is not received within 10 ms, a request for re-transmission of the data package is issued. Thus, 10 ms represents the minimum possible delay in transmission if interference occurs. This re-transmission is repeated at regular intervals until an acknowledgement of successful transmission is received, or when an internally pre-set criterion of 14 to 15 seconds is reached. At that time, Compass will judge the quality of the transmission to be marginal and suspend the communication with a "communication error" message on the PC screen. Because the fitting software stores the data after every successful transmission and validation, no existing data (settings information) will be lost.

User solution - The clinician should make sure that the TM-DEX is within 30 cm from the C4-PA hearing aids to ensure sufficient power for transmission. Moving the TM-DEX closer to the C4-PA hearing aids facilitates transmission. To continue programming, the clinician can simply exit the program, reboot the computer and log-in again to start a new programming session.

Daily Use of C4-PA hearing aids – The C4-PA hearing aids can be used either monaurally or binaurally, with or without the use of the RC-DEX (remote control). Thus, depending on the mode of use (monaural/binaural) and the availability of the RC-DEX, the type of wireless transmission may differ.

Transmission flow - For monaural hearing aid use, the only possible wireless communication is when the C4-PA is used with the RC-DEX. In this case, the communication of simple remote commands from the RC-DEX to the C4-PA hearing aid is possible.

For binaural C4-PA hearing aid use, two types of wireless communication are possible:

1. Simple remote commands from RC-DEX to the hearing aids, if RC-DEX is used.

2. Automatic data update between hearing aids.

Quality of service criteria – The criteria for different transmission modes are:

1. For remote commands (RC-DEX to hearing aid(s)) – successful and prompt transmission of commands; immunity against interference. A bit error rate better than 10^{-2} is required.

2. For data update between hearing aids – responsiveness to changing environments; immunity against interference. A bit error rate better than 10^{-3} is required.

Design considerations to ensure quality of service

1. *Simple remote commands* – Program or volume changes are sent from the RC-DEX to the C4-PA hearing aid(s) with the push of a button. Each command (including the MAC address) is sent without acknowledgement to the hearing aid(s) in a simplex or one-way manner, with a latency of (b)(4) s, seven times to increase the chance of successful reception (i.e., redundancy). The transmission is successful even if only one of the hearing aids receives one of the seven transmitted packages. CRC is also used to ensure data integrity. If two hearing aids are used (binaurally), the received remote control command will be transmitted between the C4-PA hearing aids to synchronize the setting. A BER (Bit Error Rate) better than 10^{-2} is deemed reliable. This somewhat relaxed BER requirement compared to 10^{-3} is still considered reliable because the redundancy increases the likelihood of success for the transmission.

2. *Data exchange/updates between pair of binaural hearing aids* –This continuous, automatic data update between hearing aids ensures that the programs, volume, and other parameter settings are synchronized between the two C4-PA hearing aids. Data exchange is performed continuously at a rate of 20 times per second in a semi-duplex manner to ensure accuracy of the settings on each hearing aid. The success of these transmissions is monitored by calculating the cyclic redundancy check (CRC) checksum. If the radio communication is degraded, the receiving hearing aid will wait for the next package for update (i.e., no communication for (b)(4)). If the communication is lost for more than (b)(4) (b)(4) (or (b)(4)), both hearing aids will start searching for each other and each will issue an audible verbal "partner check" alarm after 8 seconds of searching to alert the wearer. The audible alarm repeats after another 8 seconds if communication is still not established. Afterwards, the verbal messaging system will cease although the inter-ear communication will continue searching for its partners until the link is re-established (i.e., found partners). Re-activation is done automatically. It is

important to note that any degradation of data exchange/updates due to interference will not prevent the hearing aids from providing amplification: although the synchronization of settings between hearing aids may be affected by interference, the hearing aids will amplify based on the latest updated settings.

Recognizing and handling possible electromagnetic interference during use of WidexLink wireless technology (for dispensers and consumers)

Symptoms of interference or unsuccessful transmission

1. Simple remote command – the hearing aid(s) do not respond with a corresponding change in volume or program. This could result from the following:
    a. an expired battery in the RC-DEX
    b. the RC-DEX is beyond the transmission range (< 1 m)
    c. strong electromagnetic interference in the vicinity
    d. the RC-DEX and the C4-PA hearing aids are not paired

2. Data exchange between hearing aids – the wearer hears "partner check" through one or both hearing aids. This could result from:
    a. an expired battery in one of the hearing aids
    b. one of the hearing aids has loosened from the ear and may have fallen
    c. strong electromagnetic interference in the vicinity

User solution

1. Simple remote command
    a. Make sure the battery in the RC-DEX is functional. The LED on the RC-DEX should be lit. Otherwise, replace battery.
    b. Move the RC-DEX closer to the C4-PA hearing aids.
    c. Move away from the known sources of electromagnetic interference.
    d. Check with dispenser to make sure the RC-DEX is paired with hearing aids.

2. Data exchange between hearing aids
    a. Replace battery in one or both hearing aids.
    b. Make sure that both hearing aids are on the ears. Find the missing one.
    c. Move away from the known sources of electromagnetic interference.

FDA Review Note: *Appropriate design specifications and User Solutions for Quality of Service are included in the user manuals for the C4-PA hearing aids, the RC-DEX, and*

the nEARcom. We agree that it is appropriate and necessary that this information is included in the labeling to specify Quality-of-Service-related specifications and solutions to both users and clinicians.

Electromagnetic compatibility (EMC) and Wireless coexistence

The petitioner demonstrates that the C4-PA device system (consisting of the C4-PA hearing aid(s) and all of the previously described external components) is designed and tested to (1) not emit excessive amounts of electromagnetic energy (EMC emissions); (2) operate as intended without performance degradation in the presence of an electromagnetic disturbance (EMC immunity); and (3) show acceptable levels of performance in a given shared environment where other systems in that environment have an ability to perform their tasks and may or may not be using the same set of rules (wireless coexistence). See the following paragraphs and the subsequent Bench Performance Testing section for details.

Emissions: The petitioner has designed and verified WidexLink to achieve the desired level of wireless communication performance (e.g., BERs specified above) for the lowest possible power radiation level for each component: 29 pW for the hearing aids, 21 nW for the RC-DEX, and 1.2 nW for the TM-DEX. The BT used in the NOAHlink is also a low power level device which has an EIRP of 2.5 mW. The petitioner estimates that the typical duration in which the wearer is exposed to this power level is less than 10 minutes during device programming.

The petitioner claims that there is very minimal risk from direct human exposure to the electromagnetic radiation emitted by the WidexLink technology in both the daily use and programming configurations and that the human exposure risks from radiated emissions are far less concerning than those encountered from everyday commercial devices that use AC power (e.g., lights, microwave oven) or from certain consumer electronics that use longer-range wireless technology (e.g., cell phones). The petitioner provides the following arguments to support their claim of minimal risk:

1. The magnetic field strength of the WidexLink radio is extremely low (C4-PA: -54 dB µA/m; RC-DEX: -13 dB µA/m; and TM-DEX: -26 dB µA/m) compared to commercial and household devices and appliances such as fluorescent lights which can be 120 dB µA/m.

2. The petitioner analytically estimates a "worst case" value for the Specific Absorption Rate (SAR) by assuming that the antenna in the C4-PA theoretically transfers all 29 pW of the emitted electromagnetic power from the C4-PA hearing aid into 1 gram of tissue. The calculated SAR value of the hearing aids of $2.9 \cdot 10^{-8} \frac{\mathrm{W}}{\mathrm{kg}}$ is then far below the SAR limit of 1.6 W/kg @ 1 g regulated in the United States per 47 CFR 2.1091 and FCC OET Bulletin 65 supplement C, ed.

01-01. The analytical estimate of SAR is a factor of $\frac{2.9 \cdot 10^{-8}}{1.6} = 1.8 \cdot 10^{-8}$ of the SAR limit, or 77 dB below the SAR limit.

3. To reach a Maximum Permissible Exposure (MPE) of 1 mW/cm^2, per 47 CFR 2.1091 and FCC OET Bulletin 65 supplement C, ed. 01-01, the petitioner estimates the necessary distance between the transmitter and the wearer's head as $4.8 \cdot 10^{-7}$ meter (or ~0.5 µm). This is a fraction of the dimensions of the antenna and an even smaller fraction of the hearing aid housing dimensions. This suggests that the distance between the hearing aid antenna and human skin is at least a factor of 1000 times larger than this distance of 0.5 µm.

4. The petitioner estimates that the amount of radiated energy delivered to the head during 24 hours of C4-PA use is equivalent to a ~2 ms phone call using a Global System for Mobile Communications (GSM) mobile phone. These predictions are based on the following assumptions for radiated power (EIRP) and distance from the head (*R*): $EIRP_{C4\text{-}PA}$ = 29 pW; $EIRP_{GSM}$ = 0.125 W*; $R_{C4\text{-}PA}$ = 1 mm; R_{GSM} = 1 cm. Based on these parameters, the equivalent time of use for a GSM mobile phone assuming 24 hours of C4-PA use is estimated by multiplying 24 hours by the ratio of radiated power of the GSM phone to the C4-PA as follows:

   $24\,\text{h} \cdot \frac{EIRP_{C4-PA}/R^2_{C4-PA}}{EIRP_{GSM}/R^2_{GSM}}$. In terms of seconds, this is

   $$24\,\text{h} \cdot \frac{60\,\text{min}}{1\,\text{h}} \cdot \frac{60\,\text{s}}{1\,\text{min}} \cdot \frac{EIRP_{C4-PA}/R^2_{C4-PA}}{EIRP_{GSM}/R^2_{GSM}} \approx 0.002 \text{ seconds or } 2 \text{ ms.}$$

   Using the same parameters, the petitioner calculates that the amount of energy delivered during a 10 minute GSM call is equivalent to that delivered by a C4-PA hearing aid used for 12 hours a day for 1640 years.

   *upper limit of average power for GSM phones operating at 900 and 1800 MHz per International Commission on Non-Ionizing Radiation Protection [ICNIRP] 16/2009, page 15);

In addition, the petitioner contends that although there is some possibility that the emissions of the C4-PA hearing aid device system could affect the performance of another electronic medical device in the vicinity, the risk is highly unlikely. An important case that is considered is when the other medical device is a heart pacemaker. While a properly shielded pacemaker is unlikely to pick up the electromagnetic emissions from the C4-PA hearing aid(s) or the RC-DEX to cause harm to the patient, it is possible the patient may be using an older worn pacemaker which may not be properly shielded. When the RC-DEX is placed close to the pacemaker (e.g., when the RC-DEX is held close to the chest or held in a shirt pocket and a button is pressed), the transmitted signal could potentially disrupt the timing of the pacemaker, resulting in irregular pacing

stimulation and cardiac arrest. To minimize "even the slightest risk of this occurrence," the petitioner designed RC-DEX with recessed buttons to reduce the likelihood of accidental pressing. Furthermore, warnings are included in the Users' Guide to warn pacemaker users not to place the RC-DEX in a shirt pocket, not to bring the C4-PA hearing aid(s) within 15 cm) of pacemakers, and to contact the pacemaker manufacturer and healthcare provider immediately if any interference is observed.

FDA Review Note: *We reviewed the emissions safety information and deem that it is acceptable and appropriate because 1) there is negligible risk that human tissue will be significantly heated based on the radiated power levels of the C4-PA device system components, and 2) the design considerations and labeling warnings regarding pacemakers are sufficient. Additional emissions-related information is discussed below in the bench performance testing section of this memo.*

Immunity and Wireless coexistence: In addition to the design factors already described for the C4-PA device system (e.g., unique WidexLink carrier frequency matched for WidexLink transmitter and receiver; BT security; etc.), immunity of the device system to electromagnetic interference was demonstrated through bench testing. See the bench testing section below for details.

An additional design factor of the C4-PA device system that contributes to both immunity and wireless coexistence, is that binaural C4-PA hearing aids are paired with each other and with the dedicated RC-DEX unit using one unique 16-bit ID number (of a possible 65536, or 2^{16}, numbers). This unique ID is verified prior to every communication. The unique ID, together with the short range of transmission and the Quality of Service considerations for ensuring secure and efficient transmission, makes the C4-PA hearing aids highly immune to electromagnetic interference and contributes to robust wireless coexistence, during both programming and typical daily use. Moreover, wireless coexistence testing provided by the petitioner (described below) supports reasonably safe and effective coexistence performance.

FDA Review Note: *We reviewed the immunity and wireless coexistence information and determine that it is acceptable. EMC and wireless design considerations are appropriately described in the user manuals for the C4-PA, the RC-DEX, and the nEARcom.*

PRECLINICAL/BENCH TESTING

The preclinical data provided by the petitioner relate to the following areas: EMC and Wireless Safety, Software, and Biocompatibility.

EMC AND WIRELESS SAFETY

Emissions and Immunity testing: EMC emissions and immunity were tested for both the daily use components (C4-PA hearing aid(s) and RC-DEX) and programming components (C4-PA hearing aid(s) and TM-DEX and NOAHlink). Performance was compared with several standards as shown in Table 2. During IEC 60601-1-2:2007 immunity measurements, a 1000 Hz acoustic tone was presented bilaterally and hearing-aid output was monitored for this uninterrupted tone. An uninterrupted tone indicates maintenance of the link while a superimposed voice message ("partner check") indicates that the inter-ear link was impaired. Overall, the testing results indicate that the requirements specified by the standards were met, suggesting that the C4-PA device system does not emit excessive amounts of electromagnetic radiation and does not show sensitivity to unrealistically low levels of electromagnetic interference. The petitioner provides detailed test summaries, certification, and reports in their petition certifying that the following EMC emissions and immunity tests have been performed and all cases have passed:

Table 2. Summary of EMC emissions and immunity conformance tests conducted on the C4-PA hearing aids with RC-DEX or TM-DEX/NOAHlink. *****Adapted protocol: for immunity testing, the device under test was tested in only a single orientation that was deemed to represent the worst case scenario by the test house (TRaC).

Standard	Test type	Note	Test Report & Test Date C4-PA	Test Report & Test Date RC-DEX	Test Report & Test Date TM-DEX	Verdict
EN 301 489-3 V1.4.1	Immunity, RF and ESD	Standard for Low Power Transmitters in the frequency range 9 kHz – 40 GHz	(app Aa) TRaC 8F1955GEU2 1/28/2010-2/1/2010	(app Ab) TRaC 8F1955GEU1 1/28/2010-2/1/2010	(app Ac) TRaC 8F1955GEU3 1/28/2010-2/1/2010	Pass
IEC 60118-13:2004	Immunity RF Near Field immunity test	International Product std. for hearing aids to ensure adequate immunity to radio interference from mobile telephones.	(App B) Delta EMC024_10 2/26/2010	N/A	N/A	Pass
EN 300 330-2 V1.3.1	RF emissions incl. Spurious emission	EMC and radio spectrum matters for Short Range Devices in the frequency range 9 kHz – 25 MHz	(app Ca) TRaC 8F1955WEU2 1/21/2010-1/29/2010	(app Cb) TRaC 8F1955WEU1 1/21/2010-1/29/2010	(app Cc) TRaC 8F1955WEU3 1/21/2010-1/29/2010	Pass
FCC CFR 47	RF emission	USA Federal Communication	(app Da) TRaC	(app Db) TRaC	(app Dc) TRaC	Pass

Part 15, subpart C	s	s Commission (FCC) requirements to intentional radiators.	8F1955WUS2 1/25/2010-1/29/2010	8F1955WUS1 1/25/2010-1/29/2010	8F1955WUS3 1/25/2010-1/29/2010	
IEC 60601-1-2:2007 *adapted protocol	EMC emission Immunity, RF and ESD	Medical electrical equipment. General requirements for basic safety and essential performance. Electromagnetic compatibility.	(app Ea) TRaC 8F1955GEU5 1/28/2010-6/2/2010 (app Ed) TTR-003135GEU1 11/1/2010-11/4/2010	(app Eb) TRaC 8F1955GEU4 1/28/2010-6/1/2010 (app Ee) TTR-003135GEU2 (app Ef) TTR-003135GEU3 11/1//2010-11/4/2010	(app Ec) TRaC 8F1955GEU6 1/28/2010-6/2/2010 (app Eg) TTR-003135GEU4 11/1/2010-11/4/2010	Pass
ANSI C63.19-2001	Immunity RF Near Field immunity test	American National Standard Methods of measurement of Compatibility between wireless Communication Devices and Hearing Aids	(App F) Delta ANSI 024_10 2/24/2010	N/A	N/A	Pass

Wireless coexistence testing: Several wireless coexistence tests were conducted to demonstrate the immunity of a pair of C4-PA hearing aids (simulating binaural usage) and RC-DEX in the presence of interferers likely to be encountered during everyday use by a hearing aid wearer. In addition, coexistence of the C4-PA hearing aids connected to the TM-DEX/NOAHlink during programming was also tested in the presence of BT interferers which may be present in a clinical dispensing situation.

Because the C4-PA hearing aids were always used in a simulated binaural mode, inter-ear communication (along with the other features) was active. In addition, the RC-DEX remote control button was pressed at regular intervals to elicit active transmission of commands from the RC-DEX to the hearing aids. Again, any interference that impaired inter-ear communication would result in the verbal “partner check” message that would be audible to the experimenter. Any interference that impaired RC-DEX command transmission resulting in a lack of response from the hearing aid was also audible to the experimenter. In addition, sound quality was also monitored for degradation as a criterion for judging interference.

During the course of interactive review, the petitioner conducted five measures of wireless coexistence testing, with each measure examining a new set of interferers (summarized in Table 3). Interferers included the following: another C4-PA hearing aid, wireless hearing aids from several different manufacturers, several different wireless electronic devices/systems with a variety of carrier frequencies including a BT smartphone device, and an airport security metal detector. In all situations, the interferers operated at their typical frequencies and power output levels. They were also placed or evaluated at prescribed distances from the C4-PA hearing aids. The audio output was monitored for changes in sound quality (including delays) and the presence of the voice message indicating link error. The five measures with corresponding interferers that were tested and reported are as follows:

Table 3. Summary of the interferers used in the five wireless coexistence measures. Carrier frequencies of interferers are specified (where known).

Measure 1 (own aids)	Measure 2 (other aids)	Measure 3 (user scenarios)		Measure 4 (programming)	Measure 5 (airport)
Bluetooth headset • Nokia BH-216 (2.4 GHz)	**Magnum wireless earphones** • Model HP-640 (863 - 865 MHz)	**Radar – Indoor motion** • Besam R1 (24 GHz – K band radar)	**Microwave oven** • LG MP-9483SL, OBH, Elektrolux EMS2840 (2.45 GHz)	**One Bluetooth interferer during fitting** • Smartphone 93G/GSM)	**Airport security metal detector**
Mobile Phone • Samsung GT-S5600 (GSM Quadband: 850/900/1800/1900 MHz; 3 G Dualband: 900/2100 MHz)	**Phonak Excelia Art** • Model M, KeyPilot 2 remote (10.6 MHz)	**Radar – Traffic control** • Roadside radar (24 GHz – K band radar)	**2 way radio (PMR)** • Topcom twin-talker 1100 (446.00625 MHz – 446.09375 MHz)	**Two Bluetooth interferers during fitting** • Smartphone 93G/GSM) • Nokia BT headset	
C4-PA with **RC-DEX** (10.6 MHz)	**Oticon Epoq** • Model XW, Streamer remote (3.84 MHz)	**RF toll system** • KTC transceiver (5.8 GHz) • TS3201A transponder (5.8 GHz, uplink subcarriers at 1.5 or 2 MHz)	**Amateur radio installation** • Icom HF IC-transceiver (attenuator: 1.8–3.7–7.1 MHz; antenna: 14.2–21.2–28.5 MHz)	**Two Bluetooth and one GSM interferers during fitting** • Smartphone 93G/GSM) • Nokia BT headset	

	Siemens Pure • Model 700, Tek Connect remote (3.2839 MHz)	**Wireless LAN** • HP ProCurve MSM422 (2.4 GHz & 5.8 GHz) • Lenovo T61 laptop (2.4-2.5 GHz)	**RFID – ID & access** • AssaAbloy R10 reader (13.56 MHz) • HID iClass 16k CL ID card (13.56 MHz)	**Four Bluetooth and one GSM interferers during fitting** • Smartphone 93G/GSM) • Nokia BT headset • Sony Ericsson BT speaker • Samsung GSM cell phone	
		Wireless PDA/Smartphone • HP ProCurve MSM422 (2.4 & 5.8 GHz) • HTC Desire Smartphone (2.4 GHz)	**RFID theft control** • Control 1 (58 kHz / burst repetition 37.5 – 75Hz • Control 2 (13.56 MHz)		

Results of the five coexistence measures showed that none of the interferers degraded the WidexLink and/or BT transmission. In other words, the C4-PA hearing aids (binaural) and their accessories have high immunity against a range of potential interferers that may be encountered in daily use. It is noted that the interferers were operating at their typical output level. Higher intensity or smaller distances to the test hearing aids may negatively impact coexistence in ways not observed here. Other electronic devices or different device configurations could also degrade coexistence. As an added warning, the petitioner includes in the device labeling (including the user manual), the recommendation from IEC 60601-1-2:2007 on the minimal distance to avoid interferers of different frequencies and output levels.

The petitioner reports additional testing conducted with the C4-PA hearing aids that is summarized in Table 4. In this testing, several degraded performance cases were identified when either the strength of the interferer was strong and/or the distance between the interferer and the hearing aids was small. While this list is not necessarily exhaustive, sufficient warnings are included in the labeling materials, including the User Guides.

Table 4. Identified cases of interference that resulted in hearing-aid performance degradation.

Device / Technology	Comment
Mobile phone display	The display on some mobile phones can, if placed a few millimeters from the hearing aid, suspend the inter-ear communication.
Computer monitor	If the hearing aids are places less than 15 cm from some computer monitors, the inter-ear communication can be suspended.
Welding equipment	Some unspecified welding equipment can suspend the inter-ear communication.
Induction stoves	If the hearing aids are placed less than 15 cm from some induction stoves, the inter-ear communication can be suspended.
MRI scanners	MRI scanners will affect the performance of the hearing aids. We recommend the hearing aids be removed and disabled during MRI scanning.

FDA Review Note: *We reviewed the EMC and wireless testing and conclude that the results are acceptable. In addition, the petitioner appropriately describes the EMC and wireless tests conducted and the standards met in the device labeling.*

SOFTWARE

Level of Concern: The petitioner contends that the Level of Concern for the C4-PA device system is **Minor** based on their answers to the questions listed in Table 1 (Major Level of Concern) and Table 2 (Moderate Level of Concern) of the FDA guidance document, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." Consequently, the petitioner claims that any failure or design flaws in the software are unlikely to cause any injury to the patient or to the (clinician) operator.

Software Description: As described earlier in this memo, clinicians use the Compass software to fit and program the C4-PA hearing aids for patients. Compass is certified by the DS/EN ISO-13485:2003, a software development standard that ensures the development of Compass follows specific European requirements. As previously described, the Compass software controls the parametric settings on the C4-PA hearing aids through the nEARcom, the cable-free, NOAHlink Bluetooth interface. Communication between the NOAHlink and the computer is through BT. Communication between the nEARcom and the hearing aids via a short-range inductive signal at the 10.6 MHz carrier with a magnetic field strength at -26 dBμA/m. During

programming with Compass, clinicians specify the parametric values of hearing-aid programs by entering values using the keyboard of the PC. The CMOS and BiCMOS chip used in the C4-PA hearing aids is custom-made specifically for Widex.

Device Hazard Analysis: The petitioner identifies two potential hazards associated with the use of the C4-PA hearing aids: 1) the occurrence of uncomfortably loud sounds and 2) risk of electromagnetic radiation exposure to users and others in the vicinity of the nEARcom during wireless programming.

The petitioner claims that uncomfortably loud sounds to patients wearing the hearing aid(s) may cause momentary discomfort at the time of occurrence. The possibility of sounds exceeding the loudness discomfort of the patient is mitigated by limiting the hearing aid output to below the patients' loudness discomfort listening (LDL) level. This is done within the fitting algorithm itself such that the output of the hearing aid must be lower than the LDL for any input (external environmental sounds, sounds from direct audio input and telecoil). Furthermore, the petitioner states even in the worst case scenario where the clinician did not adjust MPO to below patient's LDL, the highest output from an in-the-ear hearing aid is limited to 110 dB SPL and 125 dB SPL in a behind-the-ear (BTE) hearing aid. These conservative MPO values, when interpreted with the degree of hearing loss of the patients, are not sufficient to cause any major discomfort or harm to hearing.

The second petitioner-identified potential concern associated with the use of wireless in hearing aids is the safety of the wearers (and nearby persons) from electromagnetic radiation while using the nEARcom (wireless programmer). The risk is claimed to be minimal because the output power of the device is very low. For the TM-DEX, the EIRP is 1.2 nW. For the BT in the NOAHlink, it is only 2.5 mW. Exposure to this low level of EM radiation is also limited to the time of programming, which typically lasts between 5 and 10 minutes. Please see the section on Risk to Health for further discussion on radiation risk.

FDA Review Note: *While not necessarily directly related to software, the petitioner does not identify two potential foreseeable hazards of the C4-PA hearing aid(s), each of which could arise from either sufficient levels of electromagnetic interference, or from disruptions in wireless coexistence. These hazards are (1) the delivery of (potentially unsafe) levels of acoustic stimulation and (2) degraded levels of amplification. However, the documentation provided in the petitioner's submission, namely the EMC immunity and wireless coexistence testing (described earlier), sufficiently mitigates the risks associated with these hazards.*

Software Requirements Specification: The software for fitting the C4-PA wireless hearing aids is Compass v5.1. The Compass software is written in Delphi programming language and is compatible with PCs running the Windows 98 and later platform(s). Compass requires a PC with at minimum a Pentium 1000 MHz processor, 256 MB of RAM, and 250 MB of hard disk space. Standard PC peripherals including a computer monitor and a keyboard (and mouse) are required to use Compass. Furthermore, the

previously described nEARcom wireless interface that uses both WidexLink and Bluetooth communication is required and permits communication between the C4-PA hearing aids and Compass. nEARcom uses a standard AA size battery.

FDA Review Note: *The information provided about Device Hazard Analysis sufficiently describes the safety features implemented in hardware and software for reducing the risk of overstimulation. In addition, remaining risks are sufficiently mitigated through bench testing, design, and device description. This information sufficiently documents traceability.*

Verification and Validation Documentation: The petitioner states that all software programs are certified by HIMSA (Hearing Instrument Manufacturer Software Association) to be compliant in terms of safety and security. In addition, all versions of Compass were beta-tested by internal and external test groups to identify and correct for any programming bugs before it is released. The wireless coexistence tests described previously, in addition to demonstrating coexistence and security of the WidexLink, also provide evidence of verification of the Compass software. In addition, the pilot clinical study on the Inter-ear (IE) compression reported in the Clinical study (summarized below) suggests that the IE compression algorithm functions as designed.

In addition, the petitioner states that the software platform used in the C4-PA hearing aid is the same as that used in the mind440 hearing aid (with Zen tinnitus masker), which was cleared in K080955, which provides further evidence of software validation.

Revision Level History: The petitioner appropriately describes the revisions of the Compass software generated during the course of the software development cycle, including date, version number, and changes relative to the previous version. The petitioner lists differences between the tested version of software and the released version, and provides an assessment of the potential effect of the differences on the safety and effectiveness. Latest version: Compass 5.1, Build 5128, June 14, 2010.

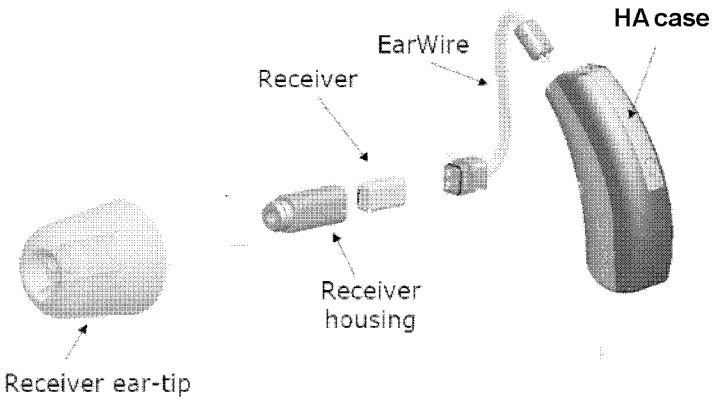
FDA Review Note: *The firmware of the device system is acceptably described at a high level through the technical description of the WidexLink and BT connectivity summarized earlier in this review memo. The EMC and wireless coexistence bench performance testing described earlier further validates the firmware of the device system. Overall, we have reviewed the petitioner's software documentation and deem that it is acceptable.*

BIOCOMPATIBILITY/MATERIALS

The C4-PA hearing aid is a receiver-in-the-canal style hearing aid composed of the following subcomponents: a BTE hearing aid case that houses the electronics, an earwire that forms a sheath around the wire which connects to the external receiver, a receiver housing that covers the receiver, and the ear-tip (Figure 5a). When the earwire is properly connected, only the wire portion is exposed. The connectors on the ends of the earwire insert into either the hearing aid case or receiver. In addition, the receiver

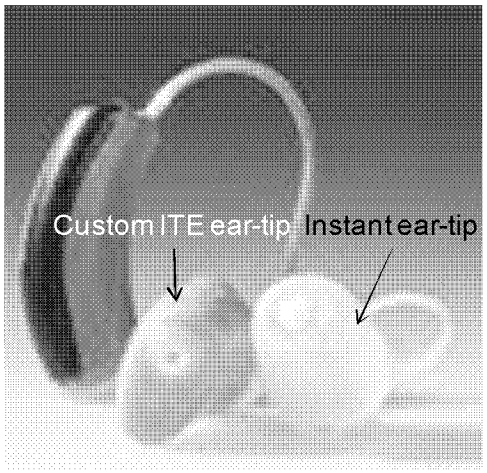
housing and the receiver insert into the eartip which is placed inside the ear canal of the wearer. The BTE case, earwire, and eartip are in direct contact with the hearing aid wearer's skin.

Figure 5a. Relations among the various external subcomponents of the C4-PA.



Two types of ear-tips are selectable - an instant ear-tip that is selected and fit by the clinician "on the spot", and a custom inside-the ear (ITE) shell ear-tip that is manufactured using the ear impression of the wearer. The two ear-tip options are shown in Figure 5b.

Figure 5b: Two types of ear-tips for the C4-PA hearing aid.



The BTE case of the C4-PA is made of a polycarbonate/ABS plastic. The petitioner contends that this material is commonly used in the hearing aid and medical device industries. The earwire is made of other plastics called PA12 and PEBA, reportedly commonly used as sheath materials for similar applications. The receiver housing is made of the plastic PBT. The instant ear-tip is made of the soft material LSR. The custom ITE ear-tip is made of an acrylic photopolymer, a plastic used to make in-the-

ear (ITE) hearing aid shells. A lacquer, MMA covers the ITE shell/custom ear-tip in the finished product.

The petitioner provides biocompatibility testing on 4 of the subcomponents separately (earwire, receiver housing, and both types of eartips). In addition, biocompatibility testing was conducted on a complete set of subcomponents consisting of the BTE casing, earwire, receiver housing, and instant ear-tip). The majority of the testing was conducted by the Medical Device Testing (MDT) Co. in Germany. The instant ear-tips were evaluated by the company Momentive Performance Materials. The ISO 10993 Standards on Biological Evaluation of Medical Devices were followed. Specifically, cytotoxicity (or the potential to retard cell growth) and skin reaction (such as irritation and delayed hypersensitivity) to intracutaneous injection and topical application of the test materials extract were studied. The petitioner contends that the testing demonstrates that the C4-PA hearing aid(s) are biologically safe.

In all studies, the materials described above were exposed to the test medium. Observations on the host reaction to the extract were made. Tables 5 to 9 summarize the studies that were conducted, the purpose of the study, the results of the study, and the standards that were followed. For ease of review, Table 5 summarizes the studies in which the complete set of subcomponents of the C4-PA (including BTE case, earwire, receiver housing, instant ear-tip) was evaluated. Each subsequent table summarizes previous testing of a specific subcomponent of the C4-PA hearing aid.

Table 5: Biocompatibility of C4-PA with a complete set of subcomponents (including case, earwire, receiver housing, and instant eartip). ISO 10993-1:2003 - Biological evaluation of medical devices – part 1: Evaluation and testing. ISO 10993-5:1999 – Biological evaluation of medical devices – part 5: Test for in vitro cytotoxicity. ISO 10993-10:2002 – Biological evaluation of medical devices – part 10: Tests for irritation and delayed type hypersensitivity. ISO 10993-12:2007 - Biological evaluation of medical devices – part 12: Sample preparation and reference materials.

Purpose	Verdict	Standards
Cytotoxicity growth inhibition	Hearing aid had no cytotoxic effects	ISO 10993-1:2003; ISO 10993-5:1999; ISO 10993-12:2007
Delayed type hypersensitivity	Hearing aid had no sensitizing properties	ISO 10993-1:2003; ISO 10993-10:2002; ISO 10993-12:2007
Irritation test	Hearing aid had no irritant effects	ISO 10993-1:2003; ISO 10993-10:2002; ISO 10993-12:2007

Table 6: Biocompatibility for Earwire used in C4-PA

Purpose	Verdict	Standards
Cytotoxicity growth inhibition	Earwire had no cytotoxic effects	ISO 10993-1:2003; ISO 10993-5:1999; ISO 10993-12:2007
Delayed type hypersensitivity	Earwire had no sensitizing properties	ISO 10993-1:2003; ISO 10993-10:2002; ISO 10993-12:2007
Irritation test	Earwire had no irritant effects	ISO 10993-1:2003; ISO 10993-10:2002; ISO 10993-12:2007

Table 7: Biocompatibility of Receiver Housing for C4-PA.

Purpose	Verdict	Standards
Cytotoxicity growth inhibition	Receiver housing had no cytotoxic effects	ISO 10993-1:2003; ISO 10993-5:1999; ISO 10993-12:2007
Delayed type hypersensitivity	Receiver housing had no sensitizing properties	ISO 10993-1:2003; ISO 10993-10:2002; ISO 10993-12:2007
Irritation test	Receiver housing had no irritant effects	ISO 10993-1:2003; ISO 10993-10:2002; ISO 10993-12:2007

Table 8: Biocompatibility of Instant ear-tips.

Purpose	Verdict	Standards
Cytotoxicity growth inhibition	Ear-tip had no cytotoxic effects	ISO 10993-1:2003; ISO 10993-5:1999; ISO 10993-12:2007
Delayed type hypersensitivity	Ear-tip had no sensitizing properties	ISO 10993-1:2003; ISO 10993-10:2002; ISO 10993-12:2007
Irritation test	Ear-tip had no irritant effects	ISO 10993-1:2003; ISO 10993-10:2002; ISO 10993-12:2007

Table 9: Biocompatibility of Custom ITE ear-tips.

Purpose	Verdict	Standards
Cytotoxicity growth inhibition	ITE ear-tip had no cytotoxic effects	ISO 10993-1:2003; ISO 10993-5:1999; ISO 10993-12:2007

Delayed type hypersensitivity	ITE ear-tip had no sensitizing properties	ISO 10993-1:2003; ISO 10993-10:2002; ISO 10993-12:2007
Irritation test	ITE ear-tip had no irritant effects	ISO 10993-1:2003; ISO 10993-10:2002; ISO 10993-12:2007

FDA Review Note: *The petitioner claims that the patient contacting materials have been widely used without any adverse effects. At the same time, the petitioner performed three tests (intracutaneous irritation, sensitization, and cytotoxicity), each of which showed no toxicity. Therefore, we determine that this information acceptably demonstrates biocompatibility of the C4-PA hearing aid for the intended use.*

CLINICAL DATA

Background: As described earlier in this memo, each of the audiological inter-ear (IE) features are enabled by default. Initial FDA review raised questions about the coordination of compression feature (or IE compression) because it is unclear how speech perception is affected since the compression characteristics of the hearing aid at the softer ear are affected differently when this feature is enabled versus disabled. During review of this petition, FDA requested that the petitioner provide clinical performance data to demonstrate that speech understanding is not poorer with IE compression enabled than with IE compression disabled. The petitioner subsequently collected pilot data from adult listeners with both symmetric and asymmetric losses. Study details, results, and conclusions are summarized in the following paragraphs.

Study Aim: The study was carried out to examine the effect of IE compression on the subjective signal-to-noise ratio (SNR) when speech was presented to one side of the binaural C4-PA hearing aid wearer. The potential differential effect of hearing-loss symmetry was also explored in this context.

Subjects: Twelve adults (6 males) with varying degrees of bilateral sensorineural hearing loss participated in the study. Among these participants, 6 participants had asymmetrical hearing loss (≥20 dB difference between ears at two or more adjacent frequencies) and 6 had symmetrical hearing loss (0-20 dB difference between ears at any given frequency). The asymmetrical hearing-loss group included 4 males and 2 females. Four participants in the asymmetric group had sloping hearing losses (mild to moderate or severe) and two had flat losses (moderate to severe). The symmetrical group included 2 males and 4 females. Three of the symmetric group participants had mild-to-moderate sloping hearing losses and 3 had moderate-to-severe sloping hearing loss. All participants were native English speakers. Four participants in the asymmetric group and all participants in the symmetrical group had previously worn hearing aids. The asymmetrical group ranged in age from 42 to 85 years, with a mean age of 62

years. The symmetrical group ranged in age from 65 to 80 years, with a mean age of 72.5 years. All participants signed an informed consent with an explanation of the purpose of the study, benefits, and risks prior to their participation. Participants were financially compensated for their participation. The C4-PA hearing aids with occluded ear tips (gumdrop inserts) were used in the study and each participant was fit binaurally.

Procedures:

Overview: ANL (Acceptable Noise Level, Nabelek) is a measure of the maximum noise level that a listener can tolerate while reportedly able to understand the speech signal. Speech stimuli were Connected Sentence Test (CST) passages. A paired comparison method was implemented to first determine the most comfortable level (MCL) for the CST passage in quiet to within 2 dB for each IE compression (on or off) and ear (left or right) condition. Speech-shaped noise from the hearing-in-noise-test (HINT) was then introduced at a level 20 dB below MCL while the CST passage was simultaneously presented at MCL. The noise level was increased by a 5-dB step size until the listener reported that s/he could no longer understand the speech. An adaptive 1-up 1-down method with a 2-dB step was used to determine the maximum noise level for which the speech was reported to still be understood. The final background noise level (BNL) for each condition was calculated as the average of last four reversals. ANL was then calculated as MCL minus BNL. The more negative the ANL, the greater the tolerance to noise, i.e., the better the performance in noise.

Audiometric data were initially obtained under headphones; masking was used as needed. Word recognition scores were obtained with the W-22 word list (1/2 lists) at the individual's MCL in quiet. Hearing aids were fit using in-situ thresholds. Hearing-aid feedback testing was completed. The gains across frequency bands of the C4-PA aids remained at default fitted settings (except for one subject's left ear for which the gain settings for soft and normal sounds were set to maximum). One master program was made available with omnidirectional microphones, noise reduction off, and TruSound stabilizer turned off. IE compression was "on" or "off" depending on the test condition and participants were blinded to the test condition.

Binaural aided MCLs were subjectively obtained for each IE compression/test ear condition for the CST passages; BNL was subsequently measured 4 times, once for each of the two IE compression conditions (on, off) and the two test ears (left, right). The speech stimuli were presented under computer control and delivered to a loudspeaker at either 90º or 270° azimuth (directed to the right or left ear). Noise was delivered to loudspeakers at 0°, 180°, and either 270° or 90º (directed to the non-test ear). This configuration allowed each ear to alternately serve as the test ear (ear with speech directed to it) with noise from the front and back as well as from the side of the non-test ear.

Results:

W-22 word recognition in quiet: Unaided word recognition on the W-22 was initially measured under headphones for each ear. Recorded male speech was presented at the MCL for each participant. On average the poor ear had word recognition scores of 72.7% and the better ear had average word recognition scores of 87.0%. The difference between the poor and the better ears in the asymmetrical group ranged from 0 to 33% with an average difference of 14.3%. In the symmetrical hearing loss group the average word recognition score was 80.3%. The difference between the right and left ears of the symmetrical hearing loss group ranged from 0 to 12%.

MCL (Most Comfortable Loudness Level): MCL was measured in soundfield for each test condition. These MCL values were used for the BNL testing. The average MCL for the asymmetrical hearing loss group was 71.3 dB SPL for the "IE on" condition and 69.8 dB SPL for the "IE off" condition. More specifically, the average MCL for the poorer ear was 74.7 dB SPL with "IE on" and 69.8 dB SPL with "IE off". The better ear averages were 67.8 dB SPL with "IE on" and 69.3 dB SPL with "IE off". For symmetrical participants, the MCL on average was 67.3 dB SPL with "IE on" and 67.0 dB SPL with "IE off".

BNL (Background Noise Level): The average BNL in the asymmetrical group for "IE on" was 73.4 dB SPL with "IE on" and 71.6 dB SPL with "IE off". The average BNL for the poorer ear was 75.3 dB SPL with "IE on" and 71.0 dB SPL with "IE off". Better ear averages were 71.5 dB SPL with "IE on" and 72.2 dB SPL with "IE off". The average BNL for the symmetrical participants was 75.3 dB SPL with "IE on" and 72.2 dB SPL with "IE off".

ANL (Acceptable Noise Level): A multivariate general linear model ANOVA (SPSS v12.0) was used to examine potential group effect on ANL with "IE on", ANL with "IE off", and IE benefit (i.e., ANL with "IE off" minus ANL with "IE on"). Results showed that there was no significant difference between the symmetrical and asymmetrical groups in ANL with "IE on" ($F(1,22)=3.30$, $p=0.08$, partial eta squared = 0.13) and with "IE off" ($F(1,22)=0.40$, $p=0.53$, partial eta squared = 0.02). However, there was a significant difference between the symmetrical and asymmetrical groups in IE benefit ($F(1,22)=12.65$, $p=0.002$, partial eta squared = 0.37). Consequently, data were analyzed separately for the symmetrical and asymmetrical groups.

As a reminder, the more negative the ANL, the more noise the wearer can tolerate. Across both ear conditions, the average ANL for the asymmetrical group was -2.8 dB with "IE on" and -2.5 dB with "IE off". The average ANL for the poorer ear was -2.2 dB with "IE on" and -1.3 dB with "IE off" (Figure 6a), even though this slight advantage with "IE on" was not statistically significant ($t(5) = -0.71$, $p = 0.51$). The better ear obtained averages of -3.3 dB with "IE on" and -3.7 dB SPL with "IE off" (Figure 6b). This difference was also not statistically different ($t(5) = 0.27$, $p = 0.79$).

Results:

W-22 word recognition in quiet: Unaided word recognition on the W-22 was initially measured under headphones for each ear. Recorded male speech was presented at the MCL for each participant. On average the poor ear had word recognition scores of 72.7% and the better ear had average word recognition scores of 87.0%. The difference between the poor and the better ears in the asymmetrical group ranged from 0 to 33% with an average difference of 14.3%. In the symmetrical hearing loss group the average word recognition score was 80.3%. The difference between the right and left ears of the symmetrical hearing loss group ranged from 0 to 12%.

MCL (Most Comfortable Loudness Level): MCL was measured in soundfield for each test condition. These MCL values were used for the BNL testing. The average MCL for the asymmetrical hearing loss group was 71.3 dB SPL for the "IE on" condition and 69.8 dB SPL for the "IE off" condition. More specifically, the average MCL for the poorer ear was 74.7 dB SPL with "IE on" and 69.8 dB SPL with "IE off". The better ear averages were 67.8 dB SPL with "IE on" and 69.3 dB SPL with "IE off". For symmetrical participants, the MCL on average was 67.3 dB SPL with "IE on" and 67.0 dB SPL with "IE off".

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Figure 6a. Average ANL for the poorer ear of the asymmetrical group participants. Right and Left ear designations indicate the test ear.

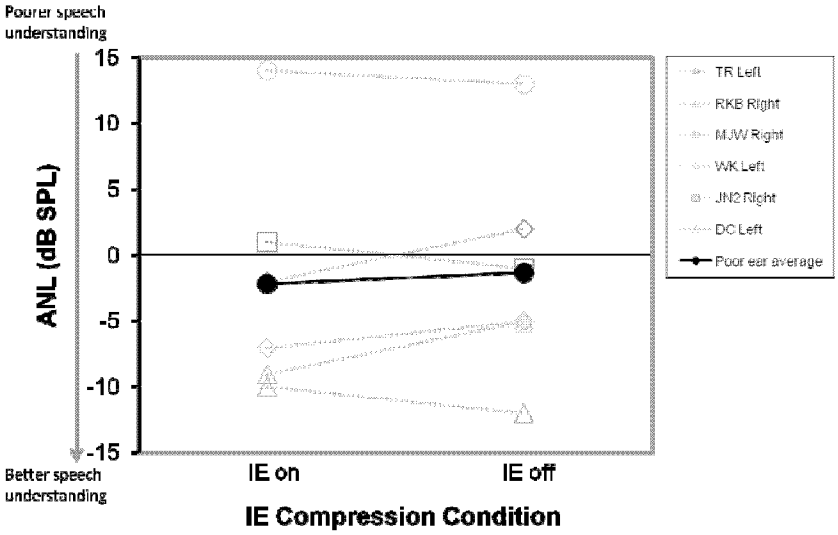
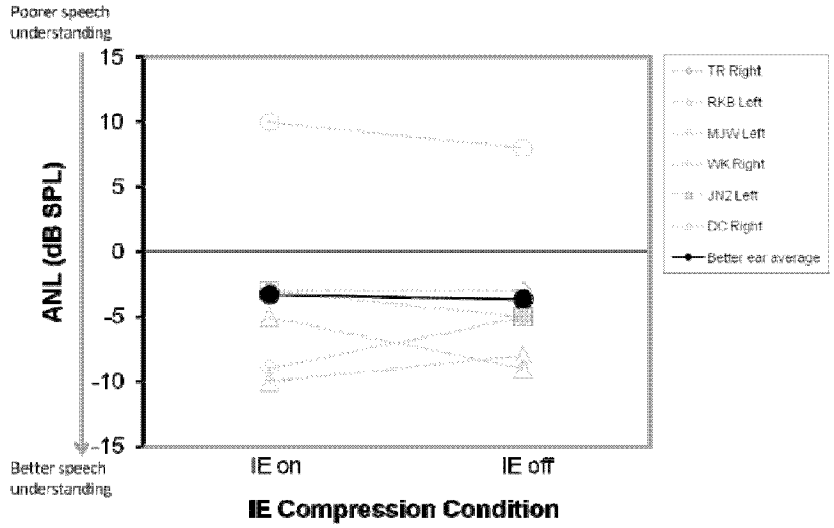
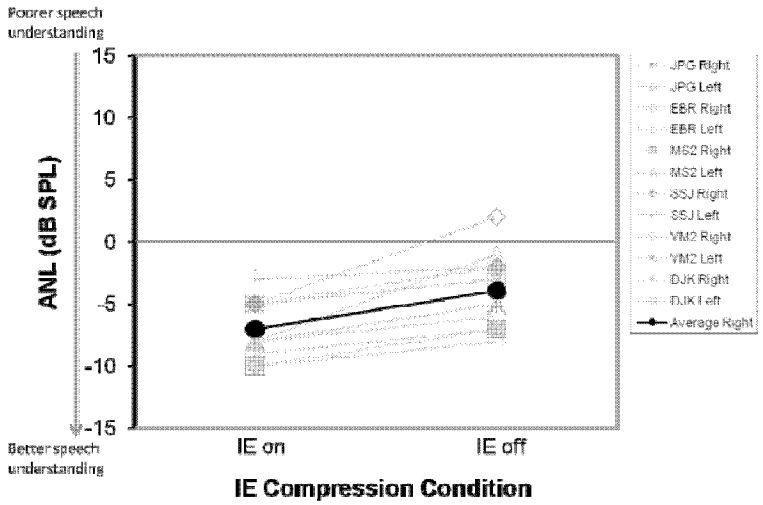


Figure 6b. Average ANL for the better ear of the asymmetrical group participants.



The average "IE on" ANL for the symmetrical participants was -7.00 dB and for "IE off" was -3.9 dB, a difference of 3.1 in favor of the "IE on" condition (Figure 7). A paired-samples t-test showed that ANL with "IE on" was significantly lower than ANL with "IE off" ($t(11) = -5.53$, $p = 0.0001$, power = 1.0).

Figure 7. Average ANL for symmetric hearing losses.



According to the petitioner, the following observations can be made on these data:

- IE-compression could potentially improve the perceived signal-to-noise ratio when speech is presented to one side of the binaural C4-PA wearer.
- There is a difference in potential benefit offered by the IE-compression between participants with a symmetrical hearing loss and those with an asymmetrical hearing loss.
    - Participants with a symmetrical hearing loss reported a significant 3 dB improvement in SNR regardless of test ear.
    - Participants with an asymmetrical hearing loss reported no significant improvement in SNR.
- There is no negative effect on speech perception in noise with IE-compression for both symmetrical and asymmetrical participants.
    - When speech was presented to the poorer ear, a non-significant improvement of 0.7 dB was reported in the asymmetric group.
    - When speech was presented to the better ear, a non-significant decrease of 0.3 dB was noted in the asymmetric group.
- Additional participants and the use of different noise backgrounds should be studied to confirm the present observations.

FDA Review Note: *The FDA concern was that Inter-ear Compression (IE compression), which dynamically shares acoustic level information between the two hearing aids of a binaural pair and adjusts compression parameters accordingly, may compromise speech intelligibility. However, the preliminary clinical study data submitted by the petitioner shows that this is not the case. In fact, when IE-compression was active for patients who had symmetrical hearing loss, a significant 3-dB improvement in SNR resulted regardless of test ear. Although no improvement or decrement in intelligibility was observed for the subjects with asymmetrical hearing loss, the small*

sample size may have precluded any observable positive outcome. The petitioner noted this limitation and intends to carry-out further studies. The petitioner does not make any claims of improved speech intelligibility in noise and states that they will not do so unless and until additional study results support such claims. Per our assessment, this is acceptable.

SPECIAL CONTROLS

The C4-PA hearing aid, as a wireless air-conduction hearing aid, 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.

3. Labeling should specify appropriate instructions, warnings, and information relating to EMC and wireless technology and human exposure to non-ionizing radiation.

CONCLUSION

I recommend that the de novo submission for the C4-PA hearing aid be approved and that the device be classified under the following:

Product Code: OSM
Device/Product Name: Wireless air-conduction hearing aid
Class: II
Regulation: 874.3305

RECOMMENDATION - I recommend that the submission be **Approved**.

(b)(6), Lead Review Date

(b)(6), Date
Chief, Ear, Nose, and Throat Devices Branch

(b)(6) Date
Clinical Deputy Director, Division of Neurological, Opthalmic, and Ear, Nose, and Throat Devices