January 19, 2022

GN Hearing A/S
Lars Hagander
Head of Regulatory Governance & Intelligence
Lautrupbjerg 7
Ballerup, DK-2750
Denmark

Re: K213424
Trade/Device Name: Jabra Enhance Plus
Regulation Number: 21 CFR 874.3325874.3325
Regulation Name: Self-fitting air-conduction hearing aid
Regulatory Class: Class II
Product Code: QDD
Dated: October 19, 2021
Received: October 21, 2021

Dear Lars Hagander:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213424

Device Name
Jabra Enhance Plus

Indications for Use *(Describe)*
The Jabra Enhance Plus self-fitting hearing aid is intended to amplify sound for individuals 18 years of age or older with perceived mild to moderate hearing impairment. It is adjusted by the user to meet the user's hearing needs. No pre-programming or hearing test is necessary. The device is intended for direct-to-consumer sale and use without the assistance of a hearing care professional.

Restricted Device (per 21 CFR 801.420 and 21 CFR 801.421).

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

K213424

Applicant Name and Address

Name	GN Hearing A/S
Address	Lautrupbjerg 7 DK-2750 Ballerup Denmark Tel: +45 4575 1111 Fax: +45 4575 1119
Official Contact	Lars Hagander Senior Director of Regulatory, Governance & Intelligence, GN Hearing Tel: +45 4575 1111 E-mail: lhagander@gnresound.com

Summary Preparation Date January 19, 2022

Device name and Classification

Trade Name	Jabra Enhance™ Plus
Common/Usual Name	Self-fitting air-conduction hearing aid
Classification Name	Self-fitting air-conduction hearing aid
Regulation Number	21 CFR 874.3325
Product Code	QDD
Classification	Class II
Panel	Ear, Nose and Throat Devices

Predicate Device Bose® Hearing Aid (DEN180026)

Device Description

The Jabra Enhance Plus is a wireless, self-fitting air-conduction hearing aid system. It incorporates microphones on the earbuds for audio input into the ear, and it can be controlled wirelessly via Bluetooth Low Energy® using the mobile app, the Jabra Enhance, installed on a compatible iPhone, iOS 14 or later. Further control of the earbuds is possible via an on-device user control button on both the Left and Right earbud. In addition to hearing aid functionality for environmental listening, the Jabra Enhance Plus earbuds can be used for placing and receiving telephone calls and for streaming audio from a compatible, Bluetooth compliant mobile device

that has been paired with the earbuds. The controls accessible through the Jabra Enhance mobile app and on the earbuds are used to configure parameters, settings, and listening modes of the earbuds. The earbuds integrate a rechargeable 3.7V/15mAh li-ion battery coin cell inside each earbud, and they are recharged by the on-the-go charging case that also serves as a carrying case. The mobile app is connected to the Internet Services that enable remote upgrades to the earbud firmware in support of continued enhancements.

Figure 1 below illustrates the supported interactions and interfaces between the earbuds, the mobile app, the charging case, and the internet service.

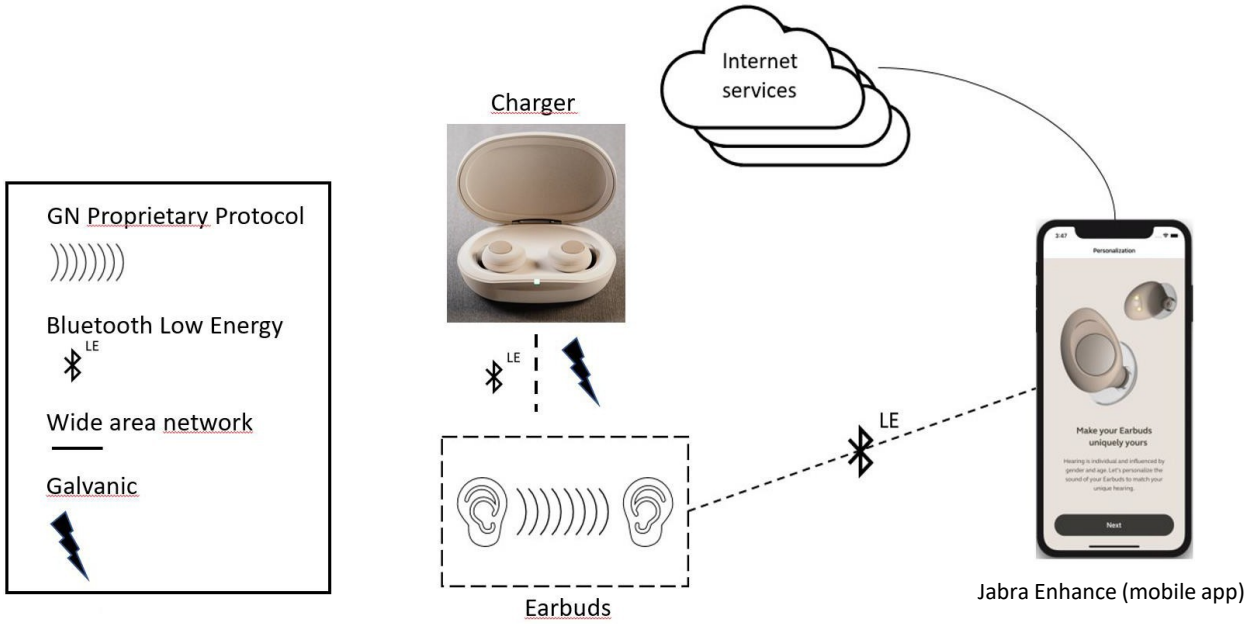


Figure 1. Jabra Enhance Plus - System interactions and interfaces between components and the internet.

Intended Use

The Jabra Enhance Plus self-fitting hearing aid is intended to amplify sound for individuals 18 years of age or older with perceived mild to moderate hearing impairment.

Indications for Use

The Jabra Enhance Plus self-fitting hearing aid is intended to amplify sound for individuals 18 years of age or older with perceived mild to moderate hearing impairment. It is adjusted by the user to meet the user's hearing needs. No pre-programming or hearing test is necessary. The

device is intended for direct-to-consumer sale and use without the assistance of a hearing care professional.

Self-Selection Labeling

Self-Selection labeling is included in the Jabra Enhance Plus IFU to mitigate the risk of improper self-selection. In summary, it addresses:

- Identifying situations in which the Jabra Enhance Plus may help you hear better.
- Identifying situations in which the Jabra Enhance Plus may not be right for the user.
- Identifying criteria that indicate the user should see a hearing professional.
- Informing the user that the Jabra Enhance Plus will not restore normal hearing.
- Informing the user that it is good health practice to have hearing loss evaluated by an appropriate healthcare professional.

Special Controls

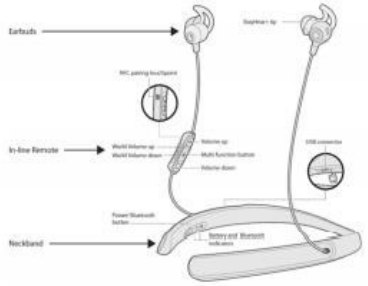
The Jabra Enhance Plus conforms to the special controls stated in 21 CFR 874.3325. The Jabra Enhance Plus satisfied these requirements through:

- Clinical data
- Non-clinical performance testing
- Human factors validation / Usability testing
- Labeling

Comparison of Technological Characteristics

The key similarities and differences between the Bose® Hearing Aid (predicate device) and the Jabra Enhance Plus (subject device) with respect to the technological characteristics are summarized in **Table 1** below.

Table 1. Key Similarities and Differences between the Bose® Hearing Aid (Predicate Device) and the JabraEnhance Plus (Subject Device).

Evaluation Criterion	Characteristic	Jabra Enhance Plus (Subject Device)	Bose Hearing Aid (Predicate Device)	Discussion
	Indications for Use	The Jabra Enhance Plus self-fitting hearing aid is intended to amplify sound for individuals 18 years of age or older with perceived mild to moderate hearing impairment. It is adjusted by the user to meet the user's hearing needs. No pre-programming or hearing test is necessary. The device is intended for direct-to-consumer sale and use without the assistance of a hearing care professional.	The Bose Hearing Aid is intended to amplify sound for individuals 18 years of age or older with perceived mild to moderate hearing impairment. It is adjusted by the user to meet the user's hearing needs. No pre-programming or hearing test is necessary. The device is intended for direct-to-consumer sale and use without the assistance of a hearing care professional.	The Indications for Use are the same.
	Intended Use	The Jabra Enhance Plus self-fitting hearing aid is intended to amplify sound for individuals 18 years of age or older with perceived mild to moderate hearing impairment.	The Bose Hearing Aid is intended to amplify sound for individuals 18 years of age or older with perceived mild to moderate hearing impairment.	The intended uses are the same.
Technological Characteristics				
	Technology	Wireless, self-fitting air conduction hearing aid	Wireless, self-fitting air conduction hearing aid	Same as predicate
	Housing	In-ear hearing aid housing. Separate left and right ear units (earbuds) with a user control push button on each unit. 	Hearing aid neckband housing that connects to both the left and right ear units with user controls on right earbud wire. 	Although the subject device hearing aid housing is wireless and in-ear instead of a neckband with wired earbuds, the difference in housing does not raise different questions of safety or effectiveness. Biological safety characteristics same as predicate device. Nonclinical data from biological safety testing and data from a clinical validation study support substantial equivalence

	Wireless communication	Wireless communication with handheld device via Bluetooth	Wireless communication with handheld device via Bluetooth	Same as predicate
AAMI TIR 69: 2017	Wireless coexistence	The GN Hearing Aid uses standard 2.4GHz Classic Bluetooth and Bluetooth Low Energy (BLE) standards to communicate between the hearing aid and the user's Bluetooth enabled device. From the risk assessment, the temporary loss of Bluetooth communication from interfering RF signals is appropriately considered a negligible risk and according to AAMI TIR 69, wireless coexistence testing is not required. Note that the interruption of device control from the App would be similar to when the user is separated from their	The Bose BMD-001 Hearing Aid uses standard 2.4GHz Classic Bluetooth and Bluetooth Low Energy (BLE) standards to communicate between the hearing aid and the user's Bluetooth enabled device. From the risk assessment, the temporary loss of Bluetooth communication from interfering RF signals is appropriately considered a negligible risk and according to AAMI TIR 69, wireless coexistence testing is not required. Note that the interruption of device control from the App would be similar to when	Same as predicate

Evaluation Criterion	Characteristic	Jabra Enhance Plus (Subject Device)	Bose Hearing Aid (Predicate Device)	Discussion
		Bluetooth enabled device.	the user is separated from their Bluetooth enabled device.	
	Wireless user control functions via mobile app	Volume Control (-12dB to +6dB) Listen Mode (Surround, adaptive, focus) Preferred filter (full, normal, clear)	Volume control Modes (everywhere, front, focused) Tone correction Left/Right balance	Bose Hearing Aid allows for Left/Right balance control, however Left/Right balance is achieved through the self-fitting process in the subject device and as such, is inherent in the self-fitted device. The additional Bose Left/Right balance does not raise different questions of safety or effectiveness. Nonclinical data from a formative usability study and data a clinical validation study support substantial equivalence.
	Demonstrate that hearing Aid device initiates Bluetooth pairing, and Bluetooth control and streaming functionality	Pairing, control, streaming verification with the paired mobile device.	Pairing, control, streaming verification with the paired mobile device.	Same as predicate
	Battery	Hearing Aid with a single cell rechargeable 3.7V/15mAh li-ion battery coin cells inside each earbud.	Hearing Aid with a single cell rechargeable 3.7V/270mAh li-ionbattery inside neckband.	While battery capacity is different, both devices are rechargeable and allow for 10 hours of battery life on a full charge, and as such the difference in battery capacity does not raise different questions of safety or effectiveness. Nonclinical data from battery safety texting and data from a

Evaluation Criterion	Characteristic	Jabra Enhance Plus (Subject Device)	Bose Hearing Aid (Predicate Device)	Discussion
				clinical validation study support substantial equivalence.
	Charging	Jabra Enhance Plus hearing aids, are charged in a proprietary On-The-Go charging case via a physical connection through Pogo contact pins in the charging case. The charging case itself contains a single cell 3.7V/129mAh li-ion battery that allows the user to charge the earbuds on-the-go without the need for being connected to a power outlet. The charging case supports both self-powered operation and/or being powered by a standard USB cable connected to a power supply. When connected to a USB power supply, the internal battery is recharged, allowing for future on-the-go charge of the earbuds.	Hearing aid is charged via USB cable connected to a power supply and to the neckband where the rechargeable battery source is located.	Charging the subject device hearing aids in a portable charging case with or without connecting the charging case to a power supply via a USB cable does not raise different questions of safety or effectiveness. Non-clinical data from a formative usability study support substantial equivalence.
	Microphones	Microphones in earbuds may, during use, be configured by the user in omnidirectional or directional modes, Surround, adaptive, focus.	Microphones in earbud may, during use, be configured by the user in omnidirectional or directional modes, everywhere, front, focused.	The subject device as well as the predicate device allow for omnidirectional and speech focus options. The subject device supports an adaptive directional mode that allows the earbuds to determine the most suitable directionality for the microphones for the given environment. The added automatic selection of directionality does not raise different questions of safety or effectiveness.

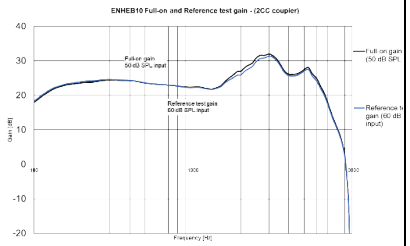
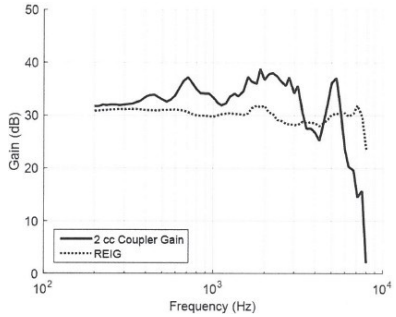
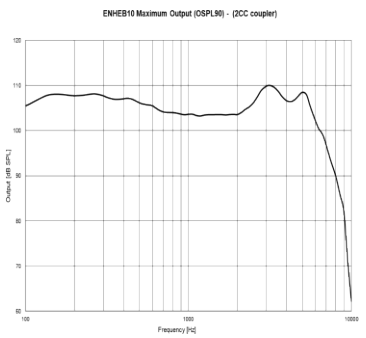
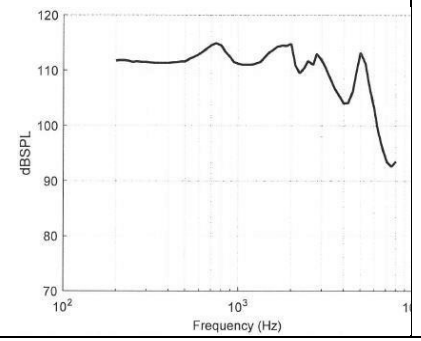
Evaluation Criterion	Characteristic	Jabra Enhance Plus (Subject Device)	Bose Hearing Aid (Predicate Device)	Discussion
				Directional Microphone options were made available to the study participants during the field trial as also was done for the predicate device. Slight differences in the directional microphone parameters between subject and predicate device do not impact the study population. Clinical data from peer-reviewed literature (Wu et al. Ear Hear. 2019) and a clinical validation study support substantial equivalence.
	Device control	On-Device user controls: - Volume up/down microphone - Volume up/down streaming - Mute - Answer mobile call - End or reject mobile call	On-Device user controls: - Volume up/down microphone - Volume up/down streaming - Power on/off button - BlueTooth pairing button	Sound adjustment features on predicate and subject devices are identical. Jabra Enhance Plus further supports mobile phone call controls. Bluetooth pairing mode is entered when the earbuds are removed from the charging case. The added call controls and different means of engaging BlueTooth pairing do not raise new questions for safety or effectiveness.

Evaluation Criterion	Characteristic	Jabra Enhance Plus (Subject Device)	Bose Hearing Aid (Predicate Device)	Discussion
				Nonclinical data from a summative usability study and data from a clinical validation study support substantial equivalence.
	Compression	17 channel wide band dynamic range compression	12 channel wide band dynamic range compression	The 5 additional channels on the subject device, as they are lumped into base, mid and treble and offer similar spectral tilt as predicate device. The 5 additional channels do not raise different questions of safety or effectiveness. Data from a clinical validation study support substantial equivalence.
	Noise reduction	Steady-state noise reduction, where background noise is filtered out from sound occurring at the microphones. Impact noise control. No support for active noise reduction.	Active noise reduction. Impact noise control.	Subject device does not support adaptive noise cancellation like predicate device, however the subject device incorporates the same algorithms already proven effective in products released to the market by GN Hearing, like Primary DI Number 05708296195077, exempt from premarket notification. While differences in the implementation of noise cancellation exist, the methods developed by GN Hearing have proven effective in products already on the market, and therefore do not raise different questions of safety or effectiveness

Evaluation Criterion	Characteristic	Jabra Enhance Plus (Subject Device)	Bose Hearing Aid (Predicate Device)	Discussion
				Noise reduction features were available to the study participants during the field trial as also was done for the predicate device. Slight differences exist in the noise reduction parameters between subject and predicate device but do not impact the study population. Clinical data from peer-reviewed literature (Wu et al. Ear Hear. 2019) and a clinical validation study support substantial equivalence.
	Feedback cancellation	Feedback canceller.	Feedback canceller.	Same as Predicate
	Telephone calls	Placing and receiving telephone calls.	Placing and receiving telephone calls.	Same as Predicate
	Mobile App	Same as Predicate with respect to iOS Not compatible with Android.	Mobile application, on handheld device (iOS or Android) used to configure parameters, settings, and listening modes.	The lack of compatibility with handheld Android devices does not raise different questions of safety or effectiveness. Nonclinical data from a summative usability study and data from a clinical validation study support substantial equivalence.
	Self-fitting method	Apply personalized gain settings based on user input and Fine-Tuning. Utilizes the validated NAL-NL2fitting algorithm.	Loudness and Fine-Tuning. Utilizes a proprietary fitting algorithm.	Subject device uses a validated NAL-NL2 fitting algorithm instead of a proprietary algorithm as used by the predicate device. NAL-NL2 is widely used by hearing care professionals to fit persons with mild to moderate hearing loss.

Evaluation Criterion	Characteristic	Jabra Enhance Plus (Subject Device)	Bose Hearing Aid (Predicate Device)	Discussion
				Legally marketed hearing aids exempt from 510(k) also embed the NAL-NL2 fitting algorithm, but these exempt hearing aids are fitted by hearing care professionals. As such the difference in fitting does not raise different questions of safety or effectiveness. Data from a clinical validation study support substantial equivalence.
	Remote Firmware update	The Jabra Enhance app allows for remote firmware update of the earbuds via the Cloud.	Unknown	Remote firmware update allows GN to maintain and improve the Jabra Enhance Plus and continuously strengthen cybersecurity as new mobile operating systems are released. Allowing for Remote Firmware Updates is assessed as part of the cybersecurity risk process, and risk mitigations are developed per the device hazard analysis, and cybersecurity associated with the RFU internet service. Patient risks associated with RFUs are understood, mitigated and the subject device is considered safe. This feature does not raise different questions of safety or effectiveness. Nonclinical data documented in the cyber risk register support

Evaluation Criterion	Characteristic	Jabra Enhance Plus (Subject Device)	Bose Hearing Aid (Predicate Device)	Discussion
				substantial equivalence.
Exposure to nonionizing radiation				
Special control 5i	Exposure to nonionizing radiation	Passes according to: IEC 62479:2010 And deemed sufficiently safe in terms of human exposure to nonionizing radiation exposure.	The Bose Hearing Aid contains a Bluetooth radio transmitter operating in the ISM band (2.400 to 2.4835 GHz) at less than 10 mW EIRP. The output power level at these operating frequencies of the Bose Hearing Aid was deemed sufficiently safe in terms of human exposure to nonionizing radiationfor the intended use.	Comparable to predicate Uses same Bluetooth technology. Nonclinical data from verification testing in accordance with IEC 62478:2010 (human exposure to electromagnetic fields) support substantial equivalence.
Electroacoustic performance				
Special control 2 ANSI/CTA 2051-2017 and underlying ANSI S3.22-2014	Electroacoustic characteristics	Frequency range: 100-8700 Hz. Maximum output (90 dB SPL input): 110 dB SPL. Equivalent noise input level: 26dB HFA Full-On-Gain (50 dB SPL input): 25 dB Latency: <15ms THD@500Hz: 0.4% THD@ 800Hz: 0.4% THD@1600Hz: 1.0% THD@3200Hz: 0.3% Per ANSI S3.22-2014 – 2cc coupler High Frequency Average (HFA) per ANSI S3.22-2014 definition, the average of gain or SPL in decibels at 1000, 1600 and 2500 Hz.	The specifications below are as reported in Sabin et al., 2020 (published results of predicate device clinical study that supported the Bose De Novo Request, **DEN180026**): Frequency range: 200-8000 Hz Maximum output (90 dB SPL input): 115 dB SPL Equivalent noise input level: 26dBInsertion Gain Targets (50 dB SPLinput) at 4000 Hz: range from 15- 35 dB (from Figure 4 in Sabin et al.) (Per ANSI/CTA 2051-2017).	Comparable to predicate and suitable for the intended user: ANSI/CTA 2051-2017 uses measurement methods and 2cc coupler from ANSI S.3-22 and as such, the frequency range, maximum output & equivalent noise input level can be compared directly to predicate device. Total harmonic distortion (THD) and latency meet requirements of ANSI/CTA 2051-2017, with requirements of <5% and <15ms respectively. Direct comparison to the predicate device is not possible as performance of predicate device on these parameters are not publicly available. The latency and total harmonic distortion meet the requirements in ANSI/CTA 2051-2017 of

Evaluation Criterion	Characteristic	Jabra Enhance Plus (Subject Device)	Bose Hearing Aid (Predicate Device)	Discussion
				<15ms and <5% respectively, and as such do not raise different questions for safety or effectiveness. Nonclinical data from testing in accordance with ANSI/CTA 2051 support substantial equivalence.
ANSI/ASA S3.22-2014 (6.8)	Frequency Response (Gain)			Comparable to predicate and suitable for the intended user. Adequate for fitting mild to moderate hearing loss as prescribed by NAL-NL2. Specification of hearing aid characteristic and testing both in accordance with ANSI S3.22-2014 support substantial equivalence.
ANSI/CTA 2051:2017 (4.1) with underlying test method ANSI S3.22:2014 (6.9) per DEN180026	Frequency Response Bandwidth	100Hz to 8700Hz	At least 250 Hz – 5 kHz	Same as predicate
ANSI S3.22:2014 (6.2) per DEN180026	Acoustic Output dB Sound pressure Level at input 90 dB Sound pressure Level (OSPL 90)			Comparable to predicate and suitable for the intended user. Adequate for fitting mild to moderate hearing loss as prescribed by NAL-NL2. Specification of hearing aid characteristic and testing both in accordance with ANSI S3.22, support substantial equivalence.

Evaluation Criterion	Characteristic	Jabra Enhance Plus (Subject Device)	Bose Hearing Aid (Predicate Device)	Discussion
ANSI S3.22:2014 (6.2) per DEN180026	Maximum Acoustic Output Sound Pressure Level Input 90dB SPL (Max OSPL90)	110 dB SPL which is less than or equal to 120 dB SPL	115 dB which is less than or equalto 120 dB SPL.	Same as predicate
ANSI S3.22:2014 (6.11) per DEN180026	Harmonic Distortion (Output Distortion)	Total Harmonic Distortion (THX) THX 500 Hz 0,4% THX 800 Hz 0,4% THX 1600 Hz 1,0% THX 3200 Hz 0,3% Results are less than 5%	Less than or equal to 5%	Same as predicate
ANSI/CTA 2051:2017 (4.4.2) per DEN180026 Test frequency = 500 Hz Test input level = 100 dB SPL Gain adjusted for output = 80 dB SPL or, if not possible, for 100 dB SPL	Input Distortion	3,5 % which is less than 5%	Less than or equal to 5%	Same as predicate
ANSI S3.22:2014 (6.12) per DEN180026	Equivalent Input Noise (EIN)	24 dB SPL which is less than or equal to 32 dB SPL	26 dB SPL which is less than or equal to 32 dB SPL	Same as predicate
ANSI/CTA 2051:2017 (4.8) per DEN180026	Latency	5.6 ms which is less than 15 ms	Less than or equal to 15 ms	Same as predicate
ANSI S3.22:2014 (6.3) per DEN180026	High Frequency Average Output Sound Pressure Level (HFA OSPL 90)	104 dB SPL	112 dB SPL	Adequate for fitting mild to moderate hearing loss as prescribed by NAL-NL2. Data from a clinical validation study support substantial equivalence.
ANSI S3.22:2014 (6.5) per DEN180026	High Frequency Average Full On Gain (HFA FOG)	26 dB	43 dB	Adequate for fitting mild to moderate hearing loss as

Evaluation Criterion	Characteristic	Jabra Enhance Plus (Subject Device)	Bose Hearing Aid (Predicate Device)	Discussion
				prescribed by NAL-NL2. Data from a clinical validation study support substantial equivalence.
ANSI S3.22:2014 (6.7) per DEN180026	Reference Test Gain (RTG)	25 dB	36 dB	Adequate for fitting mild to moderate hearing loss as prescribed by NAL-NL2. Data from a clinical validation study supports substantial equivalence.
ANSI/CTA 2051:2017 (4.10 – 4.17) per DEN180026	-Fixed or Level Dependent Frequency Equalization -Tone -Control Level Dependent Gain/Compression -SNR Enhancement -Noise Reduction -Feedback Control / Cancellation -Personalization Device -Coupling to the Ear -Wireless Connectivity	Hearing Aid Features reported.	Hearing Aid Features reported.	Same as predicate.

The results of all performance testing required as special controls demonstrated substantial equivalence of the Jabra Enhance Plus to the predicate Bose Hearing Aid. The Jabra Enhance Plus has the same intended use and fundamental technology as the predicate, the Bose Hearing Aid (DEN180026). The differences in technological characteristics do not raise different questions of safety or effectiveness.

While the proposed predicate and subject device are not identical, the technological characteristics are similar and the technological differences between the proposed predicate device and the subject device do not raise different questions of safety and effectiveness. Table 1 above identifies each of the key technological differences between the Jabra Enhance Plus and the predicate device as well as the accepted scientific testing performed for each of these differences to demonstrate substantial equivalence. The non-clinical, usability, and clinical performance testing demonstrated substantially equivalent safety and effectiveness of the Jabra Enhance Plus as compared to the predicate device.

Non-clinical Performance Testing

GN Hearing A/S conducted performance testing on the Jabra Enhance Plus to provide reasonable assurance of safety and effectiveness of the subject device as compared to the predicate device, Bose Hearing Aid (DEN180020). The standards used for non-clinical Performance testing are listed below.

- Electrical safety testing is performed according to IEC 60601-1:2005+A1:2012+A2:2020, IEC 60601-2-66:2019, IEC 60601-1-11 Edition 2.0 2015-1, IEC 62133-2 Edition 1.0 2017-02 and IEC 62368-1:2018/COR1:2020.
- Electromagnetic compatibility (EMC) testing is performed according IEC 62479:2010, ANSI IEEE C63.19-2019 and IEC 60601-1-2:2014+A1:2020.
- Radio and Telecommunication testing is performed to be in compliance with applicable parts of the FCC rules in title 47 of the CFR.
- Electroacoustic testing is performed according to ANSI/ASA S3.22-2014 and ANSI/CTA 2051:2017.

Software was developed, tested and documented in accordance with "Guidance for the content of Premarket Submissions for Software Contained in Medical Devices" (issued May 11, 2005) for a Moderate Level of Concern and with "Content of premarket Submissions for Management of Cybersecurity in Medical Devices" (Draft issued October 18, 2018).

Usability Engineering was performed in compliance with IEC 62366-1:2015.

Biocompatibility

The Jabra Enhance Plus Earbuds were tested in accordance with ISO 10993-1, FDA Guidance "Use of International Standard ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process".

The relevant biological endpoints were checked by testing the earbuds including the EarGels in their final finished form: MTS Cytotoxicity Test (ISO 10993-05:2009) , Guinea Pig Maximization Sensitization Test (ISO 10993-10:2010), Intracutaneous Study in Rabbits (ISO 10993-10:2010).

For the Charging Case, Model C-5 biological evaluation was performed in accordance with the FDA Guidance noted above and also the FDA draft guidance "Select Updates for Biocompatibility of Certain Devices in Contact with Intact Skin".

Results

The Jabra Enhance Plus Earbuds passed all tests for the relevant non-clinical performance testing and biological endpoints, namely cytotoxicity (ISO 10993-05:2009), sensitization, and intracutaneous reactivity (ISO 10993-10:2010). Similarly, usability testing and software verification and validation demonstrated mitigation of risks to an acceptable level as well as reasonable assurance of safe and effective device performance. Usability testing is discussed in more detail below.

Conclusion

Based on the results of the non-clinical performance testing and the risk management acctivities, the device system, Jabra Enhance Plus, is safe and meets performance specifications. It is also biologically safe for the user. Overall, these results, together with results from usability testing and software verification and validation, further support the risks to health are mitigated to an acceptable level and provide additional evidence of safety and effectiveness.

Clinical Data

A clinical validation study was conducted across two geographically disparate U.S. clinical audiology sites. Subjects, aged 28 to 73 years, ½ male and ½ female, were fitted bilaterally with prototype Jabra Enhance Plus hearing aids. About 66% (25/38) of the subjects had never worn hearing aids before. Study criterion was mild to moderate bilateral sensorineural hearing loss (from 250 through 8000 Hz with at least one threshold >20 dB HL and thresholds at 500, 1000, 2000 and 4000 Hz $\leq$ 55, 65, 70, and 80 dB HL, respectively). Individual audiograms covered the range from very mild/near normal to moderate/bordering on severe. Mean and standard deviation audiograms for each ear were very similar to those in the predicate Bose self-fitting hearing aid study[1].

Protocol

An in-lab session examined reliability of the device's self-fitting method (SELF-FIT) and compared it to a best-practices professional fitting of the same device (PRO-FIT). For SELF-FIT, each subject performed the procedure twice (SELF-FIT A and B). Based on hearing estimates obtained through the

device's "heard it" procedure, the device software internally set gain, frequency response, and compression using an algorithm based on the NAL-NL2 prescription[2]. For PRO-FIT, an audiologist fit the same device using *in situ* NAL-NL2 real ear aided response (REAR) targets. In the predicate Bose device study[1], NAL-NL2 was also used for the comparison. Unaided responses on a speech-in-noise test (QuickSIN[3]) and the Abbreviated Profile of Hearing Aid Benefit (APHAB) questionnaire[4] were obtained as a baseline for later aided measurements.

Subsequently, a cross-over, within-subject (repeated measures) wear-time field trial was used to evaluate validity of the self-fitting method and hearing device in terms of effectiveness in everyday use. At the end of the in-lab session, one-half of the subjects at each site wore home the devices programmed with SELF-FIT (A) settings and the other half wore home the same devices programmed with PRO-FIT. After 10-14 days, subjects returned to the clinic for aided outcome measurements (QuickSIN, APHAB). Then the devices were set to the other fitting and worn another 10-14 days, followed by a return to the clinic for aided measurements with the second fitting. Subjects were blinded as to which fitting was being worn. Device settings available for the subjects to adjust with the app were those that will be on the commercial hearing aid, including overall volume, frequency response ("spectral tilt") options, and microphone directionality. This is similar to adjustability offered in the predicate Bose device study[1] and offers fine-tuning options typical for the candidate mild to moderate hearing losses.

Effectiveness Results

Data were obtained for the initial in-lab session on 38 subjects (19 at each site). The primary endpoint for this session was REAR results. Statistical analysis revealed equivalence between SELF-FIT A and B for the replicated REAR4 (500, 1000, 2000, 4000 Hz) for both ears, indicating excellent reliability of the self-fitting test method. In terms of the fit to NAL-NL2 targets, analysis of REAR4 revealed that neither SELF-FIT A nor B was statistically equivalent to PRO-FIT within the symmetric equivalence region of ±2.5 dB difference. The greatest REAR deviation for both SELF-FIT and PRO-FIT was in the higher frequencies, as is typical in hearing aid fittings, but underfitting to target was somewhat greater for SELF-FIT, especially at 4000 and 6000 Hz. When the average REAR measure was computed based on 500, 750, 1000, 1500 and 2000 Hz (frequencies most critical for speech understanding), the difference between SELF-FIT A and PRO-FIT was reduced about 1 dB on average. Further, the root-mean-square difference from target calculated for those frequencies showed no significant difference between SELF-FIT A and PRO-FIT for the right ear, although the mismatch to target for SELF-FIT was still greater than that for PRO-FIT for the left ear. Self-fit gain was also less than professionally fit in the Bose predicate device study[1].

Despite less high-frequency gain supplied by the SELF-FIT method than PRO-FIT, statistical analysis revealed equivalence (within ± 1.5 dB) of QuickSIN scores (the secondary endpoint) across all three fitting conditions (SELF-FIT A and B, and PRO-FIT). This result indicates both validity and reliability of the self-fitting method on this performance measure.

For the wear-time field trial, complete data were obtained on 37 subjects (18 at one site and 19 at the other). The objective was to confirm that performance outcomes for the SELF-FIT condition were not inferior to those from the same devices fit by an audiologist (PRO-FIT) after a period of hearing-aid use in everyday conditions. The primary endpoint was the APHAB-global score. Results showed very similar aided mean and standard deviation values for SELF-FIT and PRO-FIT across APHAB subscales and the overall APHAB-global score. On two of the three subscales assessing speech communication (RV and BN) and the global score, mean scores were significantly improved over the unaided condition for both SELF-FIT and PRO-FIT. Analysis of the APHAB-global score revealed that SELF-FIT was

statistically non-inferior to PRO-FIT. Further, APHAB-global scores for SELF-FIT and PRO-FIT were nearly identical to those reported in the Bose predicate device study[1]. Using a custom 7-point scale, most subjects reported that they believed both the SELF-FIT and PRO-FIT conditions enhanced their listening on the telephone (58%; 19/33) and to music (67%; 22/33).

Mean and standard deviation QuickSIN scores after the wear-time trials (the secondary endpoint) also showed similar values between SELF-FIT and PRO-FIT. Performance with SELF-FIT was statistically non-inferior to that with PRO-FIT. The QuickSIN results showed essentially the same trends as those reported for the Bose predicate device study[1].

Safety results

The safety endpoint of the clinical validation study was met. There were no recorded Adverse Events (AEs) or Serious Adverse Events (SAEs) at either study site during the study.

Discussion and Summary

Repetition of the self-fitting procedure resulted in statistically equivalent REAR and QuickSIN results. These findings, together with strong and significant test-retest correlations, provide evidence that the self-fitting procedure for the Jabra Enhance Plus hearing aid is very reliable.

The SELF-FIT method did result in some underfitting to NAL-NL2 REAR targets on average relative to PRO-FIT, particularly in the higher frequencies. While it would not have been detrimental if SELF-FIT had provided more gain, the observed REAR acoustical differences between the two fitting methods were ultimately inconsequential to performance, as evidenced by good functional and field trial results. It is well known that a wide range of aided frequency responses can yield equivalent speech-in-noise performance in adults with mild to moderate hearing loss[5]. Performance when wearing the device home is considered paramount because it is more clinically meaningful than measures completed during a brief in-lab session. The field-trial data in this study illustrated both measurable and perceived benefit of the self-fitted devices. Further, other studies have also observed a preference for self-fit gain to be lower than that prescribed by NAL-NL2, especially in the higher frequencies[1,6,7]. Finally, the REAR differences between SELF-FIT and PRO-FIT in this study were within a range that could be readily compensated for by adjustments of device volume or spectral tilt using the app if the self-fitted user later prefers more gain or high-frequency emphasis.

In summary, the evidence from the clinical validation study taken as a whole provide strong support for the conclusion that the Jabra Enhance Plus hearing aid has a reliable self-fitting method and will provide the intended population of adults with mild to moderate hearing loss with functional performance that is not inferior to that provided by a professional hearing aid fitting. The findings of this clinical trial are similar to those from the Bose predicate device study[1].

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Human Factors / Usability Testing

The Jabra Enhance Plus meets the applicable requirements of IEC62366:2015 Medical devices – Application of usability engineering to medical devices.

Usability was evaluated in two formative usability studies and a summative usability study. Based on the results of the initial, internal formative Pre-Alpha 1 usability study and a subsequent, external formative usability study, the following changes were made before conducting the summative usability study:

- Updated pairing scheme in earbud firmware
- Face card with quick start guide placed in the box is updated both on the front and back
- Earbud/charging case improvements
- App improvements

Human factors validation testing performed was a summative usability test conducted for the purpose of evaluating safety and ease-of-use of the earbud and associated materials, i.e., software, instructions for use, and packaging, to identify any residual risks and propose any opportunities for improvements of the device's user interface. The summative usability study was divided into two parts, one that evaluated whether 21 participants who were not intended device users could use the external packaging and labeling to ascertain the device's contraindications, and a second functional usability study that evaluated whether 15 intended users (i.e., those with mild-moderate hearing loss) primarily to assess their ability to set-up the earbuds. The results of the testing were used to improve the Jabra Enhance Plus to a level found sufficient to conclude that the residual risk is low and has been reduced to an acceptable level. Furthermore, the residual risks and risk mitigation measures are described in the user manual in the form of cautions and warnings.

The Jabra Enhance Plus has been found to be safe and effective for the intended users, uses, and use environment.

Substantial Equivalence

The Jabra Enhance Plus has the same intended use and fundamental technology as the predicate, the Bose Hearing Aid (DEN180026). The differences in technological characteristics, summarized in Table 1 above, do not raise different questions of safety or effectiveness. For each of these technological differences, Table 1 also summarizes the accepted scientific testing performed to demonstrate substantial equivalence. Non-clinical performance testing

demonstrated equivalent safety and effectiveness with respect to electrical safety, EMC, radio/telecommunications and electroacoustic testing. Similarly, software was developed, tested, and documented in accordance with "Guidance for the content of Premarket Submissions for Software Contained in Medical Devices" (issued May 11, 2005) for a Moderate Level of Concern and with "Content of premarket Submissions for Management of Cybersecurity in Medical Devices" (Draft issued October 18, 2018). The usability testing and clinical study provided validation that risks to health have been mitigated to an acceptable level as well las reasonable assurance of safety and effectiveness and evidence of clinically meaningful benefit to a population experiencing obstacles to accessibility and affordability of hearing aids. Overall, based on the results of non-clinical, usability and clinical performance testing, risks to health have been mitigated to an acceptable level and the benefits of the Jabra Enhance Plus clearly outweigh the potential risks to health. Thereby, the performance data taken as a whole, demonstrate that the Jabra Enhance Plus is substantially equivalent to the Bose Hearing Aid with respect to safety and effectiveness.

Conclusion

The Jabra Enhance Plus is substantially equivalent to the predicate device, i.e., the Bose Hearing Aid (DEN180020) with respect to the indications for use, intended use and technological characteristics. The Jabra Enhance Plus is as safe and as effective as the predicate device for its intended use when used according to the Instructions for Use.