June 25, 2026

GN Hearing A/S
Lars Hagander
Senior Director, Regulatory Governance & Intelligence
Lautrupbjerg 7
Ballerup, 2750
Denmark

Re: K254108
Trade/Device Name: Jabra Enhance Select Self-fit (Jabra Enhance Select 550)
Regulation Number: 21 CFR 874.3325
Regulation Name: Self-fitting air-conduction hearing aid
Regulatory Class: Class II
Product Code: QUH
Dated: May 29, 2026
Received: May 29, 2026

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

SHUCHEN PENG -S

Shu-Chen Peng, Ph.D.
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K254108

Device Name
Jabra Enhance Select 550

Indications for Use *(Describe)*
The Jabra Enhance Select 550 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.

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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JABRA ENHANCE SELECT 550 510(K) SUMMARY

Submitter

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Summary preparation date: June 12th, 2026

Subject Device

Trade Name: Jabra Enhance Select 550
Common/Usual Name: Self-fitting air-conduction hearing aid
Classification Name: Self-fitting air-conduction hearing aid
Regulation Number: 21 C.F.R. §874.3325
Product Code: QUH
Secondary Product Codes: OSM, QUG
Classification: Class II
Panel: Ear, Nose and Throat Devices

Predicate Device

Predicate Device: Jabra Enhance™ Plus (K213424)

Reference Devices

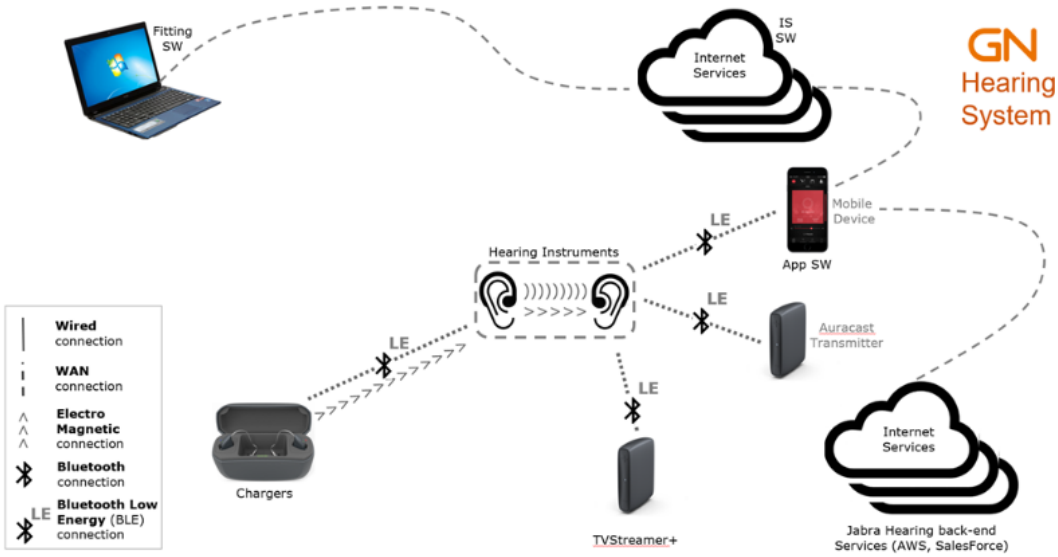
Reference Devices: Jabra Enhance Select 300 QF560S-C (510(k)-exempt under product code QUG)
ReSound Nexia NX560S-DRWC (510(k)-exempt under product code OSM)

Device Description

The Jabra Enhance Select 550 is a wireless, self-fitting air-conduction hearing aid system intended for use by individuals 18 years of age and older with perceived mild to moderate hearing loss. The Jabra Enhance Select 550 incorporates a type 4 audiometer using previously cleared Bayesian Pure Tone Audiometry self-fitting technology (K213424) and user input to derive specific independent hearing characteristics for programming the hearing aids to the end-user's hearing profile.

The Jabra Enhance Select 550 are RIE type hearing aids and incorporate microphones for picking up audio input for further processing in the embedded firmware and amplification presented to the impaired ear via the SureFit3 receiver. The hearing aids contain two wireless communication interfaces supporting ear-to-ear communication via magnetic induction, and interactions with the Jabra Enhance Select mobile app as well as supported wireless accessories via Bluetooth® Low Energy (BLE). The hearing aids are powered from integrated lithium-ion batteries that are recharged wirelessly by the charger. The Jabra Enhance Select 550 hearing aids come with a selection of domes (tulip, open, closed) and additional retention option to support the end-user with a comfortable and reliable fit.

Figure 1: Jabra Enhance Select 550 – system interaction and interfaces between components and Internet Services.



Self-fitting the Jabra Enhance Select 550 is performed via the supporting Jabra Enhance Select mobile app that utilizes BPTA self-fitting technology to derive the user's individual hearing profile, which is used to prescribe gain via the supported fitting algorithm. In addition, the user optionally has access to professional services enabling specific remote programming supporting audiogram-based fitting, as well as remote fine-tuning packages applied to the hearing aids via the Jabra Enhance Select mobile app.

Intended Use

The 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 Select 550 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.

Comparison of Technological Characteristics

The Jabra Enhance Select 550 (subject device) and the Jabra Enhance™ Plus (predicate device) share the same fundamental technology, despite being different in form factors. Both devices incorporate and allow self-fitting using the same underlying BPTA and NAL-NL2 algorithms, and the self-fitting flow, user controls and audio streaming are managed via an iOS or Android mobile app.

A high-level summary comparing the two devices can be found in the list below:

- Both devices are self-fitting hearing aids
- Both devices have identical intended use, indications for use and use environment
- Both devices utilize a mobile app supporting BPTA self-fitting flow, using NAL-NL2 and following auditory scene selection and fine-tuning adjustments
- Jabra Enhance Select 550 (subject device) are RIE type hearing aids, where Jabra Enhance™ Plus (predicate device) are ITE type hearing aids
- Jabra Enhance Select 550 (subject device) offers additional professional services
- Jabra Enhance Select 550 (subject device) offers support for streaming accessories and Auracast™
- Jabra Enhance Select 550 (subject device) offers tap control for phone call handling
- Jabra Enhance Select 550 (subject device) offers a selection of three different types of domes

The key similarities and differences between the Jabra Enhance™ Plus hearing aid (predicate device) and the Jabra Enhance Select 550 (subject device) with respect to the technological characteristics are summarized in table 1 below.

Table 1: Comparison of Jabra Enhance Select 550 (subject device) and Jabra Enhance™ Plus (predicate device)

Evaluation criterion	Jabra Enhance Select 550 (Subject Device)	Jabra Enhance™ Plus (Predicate Device)	Comparison
Product code, primary	QUH	QUH	Same as predicate. Predicate device received a product code change adding QUH based on K213424 amendment letter A001.

Product code, secondary	OSM	N/A, no secondary product code	The subject device has an optional feature that allows for the hearing aid to be adjusted remotely by hearing care professionals. The hearing care professional adjusts the device remotely through Fitting Software (FSW), which is under the product code OSM, special controls §874.3305, and exempt from 510(k). This feature is consistent with the 510(k)-exempt ReSound Nexia.
Product code, secondary	QUG	N/A, no secondary product code	The subject device has an optional feature that allows for the hearing aid to be used out of the box with gains matching typical mild-to-moderate hearing loss, which is under the product code QUG, special controls §874.3305, and exempt from 510(k). This feature is equivalent to the 510(k)-exempt Jabra Enhance Select 300 QF560S-C.
Regulation	21 C.F.R. §874.3325	21 C.F.R. §874.3325	Same as predicate.
Classification name	Self-fitting air-conduction hearing aid	Self-fitting air-conduction hearing aid	Same as predicate.
Intended Use	The Jabra Enhance Select 550 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 Jabra Enhance Plus self-fitting hearing aids are intended to amplify sound for individuals 18 years of age or older with perceived mild to moderate hearing impairment.	Same as predicate.
Indications for Use	The Jabra Enhance Select 550 self-fitting hearing aid is intended to amplify	The Jabra Enhance Plus self-fitting hearing aids are intended to amplify sound	Same as predicate.

	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.	for individuals 18 years of age or older with perceived mild to moderate hearing impairment. They are 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.	
Power source	Build-in lithium-ion battery 3.7V,18.5mAh	Build-in lithium-ion battery 3.7V, 17mAh	Different. The subject and predicate devices use similar rechargeable batteries that allow for greater than 10 hours of battery life on a full charge. While the battery technology is the same, they use different batteries. Nonclinical performance data from testing in accordance with consensus standards IEC 62133-2 and ANSI/CTA 2051:2017 supports substantial equivalence.
Labelling	Includes requirements in 21 C.F.R. §800.20	Includes requirements in 21 C.F.R. §800.20	Same as predicate.
Housing	Receiver In Ear (RIE) with push button on each device. 	In The Ear (ITE) with push button on each device. 	Different. Subject device differs in housing style from the primary predicate device. Although the subject device hearing aid housing is a wireless RIE hearing aid, the difference in housing does not raise different questions of safety or effectiveness as supported by Human Factors Engineering/Usability Engineering Summary. Additionally, both housing styles are tested to the same electroacoustic consensus standards (ANSI/ASA S3.22 via reference in ANSI/CTA 2051, ANSI/ASA S3.6) and provide the same insertion gain taking microphone location into account as

			determined by electroacoustic testing. Nonclinical data from human factors, electroacoustic and biocompatibility testing support substantial equivalence.
Acoustic characteristics	Frequency range: <200 - >8000 Hz Maximum output (90 dB SPL input): 116 dB SPL. Equivalent noise input level: 21 dB SPL HFA Full-On-Gain (50 dB SPL input): 47 dB Latency: <15ms THD: <5.0% HFA FOG: 47dB 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. Complies with ANSI CTA 2051.	Frequency range: 100-8700 Hz. Maximum output (90 dB SPL input): 110 dB SPL. Equivalent noise input level: 26dB SPL HFA Full-On-Gain (50 dB SPL input): 25 dB Latency: <15ms THD: <5.0% HFA FOG: 26dB 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. Complies with ANSI CTA 2051.	Different. Although subject device can apply more gain, the gain is applied by NAL-NL2 fitting rule in accordance with targeted perceived mild-to-moderate hearing loss. Nonclinical performance data from testing in accordance with consensus standards ANSI/CTA 2051, ANSI/ASA S3.22 support substantial equivalence.
Self-fitting method	Application of BPTA personalized gain settings based on user input and following fine-tuning. Utilizes the validated NAL-NL2 fitting algorithm.	Application of BPTA personalized gain settings based on user input and following fine-tuning. Utilizes the validated NAL-NL2 fitting algorithm.	Same as predicate.
Out of box gain settings	Mild to moderate hearing loss gain profile	5dB flat gain profile	Different. Subject device comes pre-programmed with gain settings for mild-to-moderate hearing loss, where predicate device has flat 5dB gain. Should a user continue with or revert to default gain settings, they are still provided with access to controls that allow them to adjust the hearing aids to their preference (e.g. over-all volume control, equalizer, preferred filter). Additionally, from the default gain settings, end

			users still have the option to select the self-fitting option (primary fitting flow) and the audiogram-based fitting flow (alternative fitting flow) for recommended options to obtain a gain profile target to their specific hearing characteristics. Nonclinical performance data in accordance with consensus standard ANSI/CTA 2051 data and data from human factors and testing support safe and effective operation, raises no new questions about safety and effectiveness and supports substantial equivalence.
Wireless	Ear-to-Ear communication and streaming via magnetic induction Wireless communication and streaming with a mobile device via Bluetooth®. In addition, device is Auracast™ compatible. Auracast™ is a Bluetooth® capability that allows for public broadcasting of audio to devices that can receive Bluetooth® streaming.	Ear-to-Ear communication and streaming via magnetic induction Wireless communication and streaming with a mobile device via Bluetooth®.	Different. The JES 550 hearing aid can function as an Auracast™ receiver; however, the JES mobile app does not function as an Auracast assistant. As Auracast™ functionality is optional and dependent on third-party applications not provided or controlled by GN Hearing, it is not included in the usability validation of the subject device. Use of Auracast™ does not impact the core safety or performance of the hearing aid, and failure to use or configure Auracast™ does not affect the intended use of the device. The difference raises no new questions about safety and effectiveness.
Charging	On-the-go charger supporting wireless charging.	On-the-go charger supporting contact charging.	Different. Subject device uses inductive charging compared to charging via contacts. Method of charging does not raise different questions of safety or effectiveness.

			While capacity of charging cases is different, amongst devices, capacity does not raise different questions of safety or effectiveness according to performance testing. Non-clinical performance data from bench testing pertaining to EMC and EMT per consensus standards IEC60601-1, IEC 62368, IEC 60601-2-66 IEC 60601-1-11. IEC 62133-2 and IEC 60601-1-2 supports substantial equivalence, including charging is summarized in the EMC, Wireless, Electrical, Mechanical, and Thermal Safety
Mobile app support	iOS, Android	iOS	Different. Subject device supports iOS and Android, where predicate device supports iOS. The presence of compatibility with handheld Android devices does not raise different questions of safety or effectiveness according to performance testing. Identical interfaces between iOS and Android supported by non-clinical data from verification supports 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 - Phone call tap control	On-Device user controls: - Volume up/down microphone - Volume up/down streaming - Mute - Answer mobile call - End or reject mobile call	While both devices have an on-board push button, the subject device also has an accelerometer that supports ”tap control” that allows the user to answer mobile calls by tapping the hearing aid instead of using the push button. The addition of tap control does not raise any new questions of safety or effectiveness. The impact of human factors on safety and performance of the subject device has

			been assessed, evaluated, and successfully mitigated for ensuring that the product can be used safely and effectively. The human factors / usability engineering program activities supports substantial equivalence. The difference raises no new questions about safety and effectiveness.
Mobile app device control	Mobile app user controls: - Volume up/down accessory - Auditory scene selection - Spectral tilt - Equalizer - Apply remote fine-tuning packages from professional services	Mobile app user controls: - Volume up/down accessory - Auditory scene selection - Spectral tilt - Equalizer	Different. Subject device offers professional services in addition. Nonclinical data from human factors study and verification testing shows users can navigate the supported fitting flows and supports substantial equivalence.
Noise reduction	Active noise reduction Impact noise reduction	Steady-state noise reduction, where background noise is filtered out from sound occurring at the microphones Impact noise control	Similar. Subject device active noise reduction where predicate device offers steady-state noise reduction, both means of reducing noise and enhancing speech clarity. Nonclinical data from verification testing supports substantial equivalence. The difference raises no new questions about safety and effectiveness.
Feedback cancellation	Active digital feedback canceller	Active digital feedback canceller	Same as predicate.

Performance Testing

Performance testing was conducted on the Jabra Enhance Select 550 to demonstrate that the device is as safe and effective as the predicate device.

GN Hearing has conducted non-clinical tests on Jabra Enhance Select 550 following the same foundation of recognized consensus standards as the predicate device to assess performance in electrical safety, EMC, electromagnetic safety, electroacoustic performance, biocompatibility, device verification and human factor testing. Software follows the same self-fitting flow and methods for self-assessed individual hearing profile as the predicate device utilizing the same NAL-NL2 fitting rule. New professional services have been assessed in an abbreviated summative usability study showing users can navigate the different fitting methods.

The non-clinical performance testing is summarized in the below table.

Table 2: Non-clinical performance testing

Standard	Domain	Result
IEC 60601-1:2005+A1:2012+A2:2020 CSV IEC 60601-1-2:2020 IEC 60601-1-11:2015+AMD1:2020 CSV IEC 60601-2-66:2019 IEC 62368-1:2023 ANSI IEEE C63.19:2019 FCC 47 C.F.R. part 15 FCC 47 C.F.R. part 18 IEC 62133-2:2017	Electrical safety & EMC	Pass
IEC 62311:2020 IEEE C95.3:2021 FCC 47 C.F.R. part 2	Electromagnetic safety / EMF safety	Pass
ANSI/ASA S3.22:2014 ANSI CTA 2051:2017 21 CFR §874.1050 ANSI S3.6:2018 21 C.F.R. §800.30 IEC 60118-0:2022	Electroacoustic performance	Pass
ISO 14971:2019 AAMI TIR57:2016	Risk management	Resulting risk controls: Pass
ISO 10993-1:2018 ISO 10993-5:2009 ISO 10993-10:2021	Biocompatibility	Pass
IEC 62366-1:2020 CSV	Usability / human factors	Pass
ISO 20417:2021 ISO 15223:2021 21 C.F.R §800.30	Labelling	Pass

Jabra Enhance Select 550 passed all relevant non-clinical performance testing and met applicable biological endpoints required for product code QUH. Usability and software verification and validation demonstrated effective and consistent use despite the technological differences introduced with the new form factor.

Professional services and pre-fit gain profile are supported by the Jabra Enhance Select 550 under the 510(k)-exempt OSM and QUG product codes.

Electroacoustic measurements show strong consistency between the performance of the Jabra Enhance Select 550 (subject device) and Jabra Enhance™ Plus (predicate device). Substantial equivalence has been established through measurements of ANSI/ASA S3.6 In-situ presentation levels comparison and NAL-NL2 fitting algorithm gain comparison, determining that both products present tones with acceptable consistency between measurements and thereby are suitable for deriving BPTA self-fitting determined audiograms required as input to the NAL-NL2 fitting algorithm. Comparisons of final Jabra Enhance™ 550 calibration to the Jabra Enhance Plus through electroacoustic measurements of insertion gain using artificial ear and an occluded ear simulator with pure tone and speech stimulus demonstrate the devices despite their technological difference in form factor, domes (tulip, open, closed) and microphone location have similar acoustic output, resulting in similar sound pressure level being delivered to the ear canal, which yields comparable performance for the end user. The variation in sound pressure associated with the three interchangeable domes is within the expected range and does not substantially affect performance, remaining well within the dynamic range of the mobile app controls for frequency response and overall gain adjustment available to the end user.

Overall, performance testing demonstrated no new questions of safety and effectiveness resulting from any technological differences.

Substantial Equivalence Discussion

The Jabra Enhance Select 550 has the same Intended Use, Indications for Use and fundamental technology as the predicate, Jabra Enhance™ Plus (K213424). The differences in technological characteristics do not raise different questions of safety or effectiveness.

The clinical results presented in K213424 demonstrate that the BPTA self-fitting method used in the predicate Jabra Enhance™ Plus provides outcomes comparable to those of professional fitting for adults with mild to moderate hearing loss. Because the BPTA self-fitting method and NAL-NL2 fitting rule used in the Jabra Enhance Select 550 are the same as those used in by the predicate device, the prior clinical data for Jabra Enhance™ Plus can be leveraged to support the conclusion that the Jabra Enhance Select 550 is substantial equivalent given the primary change of form factor was found to be substantial equivalent through electroacoustic performance testing.

Non-clinical performance testing demonstrated substantial equivalence with the predicate device with respect to electrical safety, EMC, radio/telecommunication and electroacoustic testing. Software was developed, tested, and documented in accordance with “Content of Premarket Submissions for Device Software Functions” (issued June 14, 2023) for Basic Documentation level and with “Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions” (issued June 26, 2025). The usability testing provided validation that risks to the end-user health have been mitigated to an acceptable level as well as reasonable assurance of safe and effective use. Jabra Enhance Select 550 relies on predicate device clinical evidence for meaningful benefit to a population experiencing obstacles to accessibility and affordability of hearing aids and bench testing showing comparable insertion gain across the subject device RIE form factor compared to the predicate device ITE form factor, thereby ensuring the acoustic output is substantially equivalent between subject and the predicate device. The selection of ear coupling options does not raise new questions of effectiveness given the magnitude of the acoustic differences and the provided controls.

Results of non-clinical performance, usability and electroacoustic performance testing shows the Jabra

Enhance Select 550 complies with the same consensus standards as the predicate device, meets the 21 C.F.R. 874.3325 requirements and as a whole demonstrate that risks to health have been mitigated to an acceptable level and the benefits of the Jabra Enhance Select 550 clearly outweigh the potential risks to health. The non-clinical performance data and usability study demonstrate substantial equivalence to the predicate device.

Labelling summary

Labelling meets special controls of 21 C.F.R. § 874.3325 and is done in accordance with 21 C.F.R. § 800.30. Labelling underwent human factor testing confirming differences to predicate device user interfaces, and labelling was found to support correct and consistent use of the device. Human factor testing did not raise new questions of safety and effectiveness.

Conclusion

The GN Hearing self-fitting hearing aid Jabra Enhance Select 550 is as safe and effective as the predicate Jabra Enhance™ Plus (K213424). The Jabra Enhance Select 550 self-fitting hearing aids have the same intended use and indications for use, and similar technological characteristics and principles of operation as its predicate device.

Technological differences in form factor and usability between the subject and predicate devices raise no new questions of safety or effectiveness, as demonstrated in bio compatibility testing, electroacoustic bench testing and an abbreviated summative usability test. New professional services introduced with Jabra Enhance Select 550 supported under the OSM product code and pre-programmed mild-to-moderate hearing loss gain settings supported under the QUG product code have same technological characteristics as existing legally marketed devices and raise no new safety or effectiveness questions as demonstrated through performance, verification and usability test. Tap control of phone calls and streaming functionality introduced with the Jabra Enhance Select 550 were determined through performance and verification tests not to raise new questions of safety and effectiveness.

The Jabra Enhance Select 550 meets all special controls and is determined to be as safe and effective as the predicate device.