August 12, 2022

WSAUD A/S
% John Smith
Partner
Hogan Lovells US LLP
Columbia Square, 555 Thirteenth Street, NW
Washington, District of Columbia 20004

Re: K220403
Trade/Device Name: Vibe SF Self-Fitting Hearing Aid
Regulation Number: 21 CFR 874.3325
Regulation Name: Self-Fitting Air-Conduction Hearing Aid
Regulatory Class: Class II
Product Code: QDD
Dated: July 14, 2022
Received: July 14, 2022

Dear John Smith:

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 of 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)*

K220403

Device Name

Vibe SF Self-Fitting Hearing Aid

Indications for Use *(Describe)*

The Vibe SF 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 through software tools. The device is intended for direct-to-consumer sale and use without the assistance of a hearing care professional.

The EasyFit self-fitting web application is intended to support self-fitting and fine-tuning of the Vibe SF hearing aid.

Restricted Device (per 21 CFR 801.420 and 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human
Services Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

WSAUD A/S's Vibe SF Self-Fitting Hearing Aid

Submitter

WSAUD A/S
Nymøllevej 6
DK-3540 Lynge
Denmark
Phone: 0045 21370938
Contact Person: Kristine Klitgaard Pedersen

Date Prepared: August 12, 2022

Name of Device: Vibe SF Self-Fitting Hearing Aid

Common or Usual Name: Hearing Aid

Classification Name: Self-Fitting Air-Conduction Hearing Aid (21 CFR 874.3325)

Regulatory Class: Class II

Product Code: QDD

Predicate Device:	Bose Corporation	Bose Hearing Aid	DEN180026
Reference Device:	Sivantos, Inc.	Signia Silk 1X	Class II 510(k)-Exempt Wireless Hearing Aid

Device Description

The Vibe SF Self-Fitting Hearing Aid ("Vibe SF") is a self-fitting air conduction hearing aid that is intended to compensate for impaired hearing and incorporates technology, including software, that allows users to program their hearing aids. This technology integrates user input with a self-fitting strategy and enables users to independently derive and customize their hearing aid fitting and settings.

The Vibe SF hearing aid is based on WSAUD's wireless hearing aid series Signia Silk 1X (regulated under 21 C.F.R. § 874.3305). However, unlike standard wireless air-conduction hearing aids, the Vibe SF is intended to be sold directly to the end-user without involvement of a hearing care professional. Briefly, the self-fitting hearing aid system consists of two components:

a) A wireless hearing aid with a self-fitting feature (Vibe SF); and
b) A mobile web application (EasyFit) to support the self-fitting and fine-tuning of the hearing aid.

The Vibe SF wireless hearing aid hardware includes: Ear pieces (click sleeves), housing, circuit board, battery, chip, and electroacoustic components. The subject device is fitted for

bilateral use with a left and right device. Left and right hearing aids are able to communicate with each other over a magnetic inductive wireless link. The instant fit in-the-ear (ITE) style of the Vibe SF hearing aid uses Click Sleeves in 4 different sizes to couple with the ear canal. The hearing aids are marked with 'R' for right and 'L' for left, and are powered by standard (non-rechargeable) Zinc-Air batteries (size 10A). The Vibe SF hearing aid includes software that communicates with the EasyFit app to provide self-fitting functionality.

The Vibe SF is fitted by the user through the EasyFit self-fitting web application, which is run on an Internet browser on the user's mobile device (smartphone or tablet with iOS or Android operating system). The EasyFit self-fitting web application guides the user through the self-fitting procedure and also allows the user to set audiological gain parameters and preferred settings on the Vibe SF Hearing Aid. In addition, a software application (app for iOS and Android) called *Vibe* app is available as remote control for adjusting volume during daily use.

Indications for Use

The Vibe SF 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 through software tools. The device is intended for direct-to-consumer sale and use without the assistance of a hearing care professional.

The EasyFit self-fitting web application is intended to support self-fitting and fine-tuning of the Vibe SF hearing aid.

Summary of Technological Characteristics

Both the subject (Vibe SF) and the predicate device (Bose Hearing Aid) are self-fit direct-to-consumer hearing aids indicated for individuals 18 and older with perceived mild to moderate hearing impairment. At a high level, the subject and predicate devices are based on the following same technological elements:

- Self-fit hearing aid.
- Home healthcare environment use.
- Software to support self-fitting and fine-tuning of the hearing aid.
- Software platform compatibility (iOS, Android).

The following technological differences exist between the subject (Vibe SF) and predicate device (Bose Hearing Aid):

- Form factor. Vibe SF has an in-the-ear design while Bose Hearing Aid has a head band design.
- Replaceable battery. Vibe SF uses zinc air batteries and is non-rechargeable. Bose Hearing Aid is rechargeable.
- Proprietary fitting algorithm for self-fitting.
- Wireless technologies. Vibe SF has a proprietary e2e (ear-to-ear) wireless technology. Bose Hearing Aid uses Bluetooth.

A table comparing the key features of the subject and predicate devices is provided below.

	Subject Device: Vibe SF Self-Fitting Hearing Aid (K220403)	**Predicate Device: BOSE® Hearing Aid (DEN180026)**	**Discussion**
Manufacturer	WSAUD A/S	Bose Corporation	Different legal entities
FDA Product Code	QDD	QDD	Same
Classification Regulation	21 CFR 874.3325	21 CFR 874.3325	Same
Indication for use	The Vibe SF 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 through software. 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.	Same intended use. Nearly identical indication for use.
Physical Description	In-The-Ear (ITE)	Flexible neckband housing Earbuds are connected to the neckband by flexible wires and on each earbud is mounted a Bose StayHear+ eartip; three sizes of tips are available.	Different form factor. Biological safety and human factors testing support substantial equivalence.
Maximum Output Characteristics	Less than or equal to 114 dB SPL (2 cc coupler)	Less than or equal to 120 dB SPL	Adequate for fitting moderate hearing loss (55 dBHL) as prescribed by NAL-NL2
HFA-FOG	45 dB	43 dB	Adequate for fitting moderate hearing loss (55 dBHL) as prescribed by NAL-NL2
Power Source	Powered by a zinc-air 1.3 V, 1.2 mAh battery	Powered by a rechargeable 3.7 V, 250 mAh Li-ion battery pack	Predicate was rechargeable; subject device uses off-the-shelf disposable hearing aid batteries. Acoustic measurements support substantial equivalence.
Labelling	Includes applicable requirements of 21 CFR 801.420 and 801.421.	Includes applicable requirements of 21 CFR 801.420 and 801.421.	Same
Reprocessing	Non-sterile. The hearing aid and ear piece (click	Non-sterile. The Earbud nozzles and Neckband	Same

	Subject Device: Vibe SF Self-Fitting Hearing Aid (K220403)	**Predicate Device: BOSE® Hearing Aid (DEN180026)**	**Discussion**
	sleeve) may be wiped daily with a soft, dry tissue.	may be wiped with a soft, dry cloth. StayHear+ tips may be rinsed with warm water and thoroughly dried before attaching them to the earbuds.	
Biological evaluation	A biological evaluation covering all components with skin contact has been conducted per ISO 10993-1, ISO 10993-5 and ISO 10993-10.	Biocompatibility tested: MEM elution Cytotoxicity per ISO 10993-5 and Irritation and Skin sensitization per ISO 10993-10.	Same
Self-fitting strategy	For the initial setup, users run an acoustic profiling test using the hearing aid devices. The initial setting is selected based on the identified profile. The user adjusts the setting for comfortable loudness impression. For the fine tuning the user can select from some pre-defined improvement areas. The application running on a mobile phone web browser uses the current setting and the desired improvement to generate a new setting. The user is able to acoustically compare both settings and select the one which is preferred for further use.	Users can control and customize signal processing parameters to their hearing needs via the Bose user interface, which consists of two Dimension-Reduced Controllers (DRCs) (“Loudness” and “Fine Tuning”) implemented in an application running on a mobile device.	Both use proprietary algorithms for self-fitting. Clinical testing supports substantial equivalence.
21 CFR 874.3325 Special controls	Includes applicable requirements for special controls for 21 CFR 874.3325	Includes applicable requirements for special controls for 21 CFR 874.3325	Same
21 CFR 874.3305 Special controls	Includes applicable requirements for special controls for 21 CFR 874.3305	Includes applicable requirements for special controls for 21 CFR 874.3305	Same

Performance Data

Non-Clinical Testing Summary

Performance testing was conducted to demonstrate that the Vibe SF Self-Fitting Hearing Aid is as safe and effective as the Bose Hearing Aid. WSAUD conducted a series of non-clinical tests on the Vibe SF to assess electrical safety, EMC, wireless coexistence, electroacoustic performance, usability, biocompatibility, and software. The results are summarized in the table below:

Test Standard/Method	Test Purpose/Description	Result
ISO 10993-1:2018 ISO 10993-5:2009 ISO 10993-1:2010	Biocompatibility	Pass
IEC 62304:2006+A1:2015	Software	Pass
IEC 60601-1:2005/AMD1:2012/AMD2:2020 IEC 60601-2-66:2019 IEC 60601-1-11:2015/AMD1:2020	Electrical Safety	Pass
IEC 60601-1-2:2014/AMD1:2020	Electromagnetic Compatibility	Pass
AAMI TIR 69:2017 ANSI C63.27:2017	Wireless Coexistence	Pass
ANSI/ASA S3.22:2014 ANSI/CTA 2051:2017	Electroacoustic	Pass
IEC 60601-1-6:2010/AMD1:2013/AMD2:2020 IEC 62366-1:2015/AMD1:2020	Usability Engineering	Pass

In all instances, the Vibe SF Self-Fitting Hearing Aid functioned as intended and results observed were as expected.

As noted in the above table, a human factors validation test was performed to demonstrate that the Vibe SF can be used safely and effectively, per its labeling, by representative intended users, for the intended uses and in the intended use environments. The results indicated that any remaining residual use-related risks were acceptable and were outweighed by the benefits derived from use of the device.

Labeling mitigations were implemented on the Vibe SF box labeling and in the Vibe SF Instructions for Use ("IFU") to help potential users with the self-selection process. These included clarification of the intended users of the device, identification of situations in which the device may and may not be appropriate, and informing users of the device's limitations and the value of a professional hearing loss evaluation.

Clinical Testing Summary

WSAUD performed a pivotal clinical study to assess the patient-reported benefit from using the self-fitted Vibe SF hearing aid versus the same form factor hearing aid fitted by a hearing care professional ("HCP"). The study was designed as a Single-arm randomized crossover study with patients serving as their own control. It was blinded for some of the secondary endpoints. There was 1 study site in the United States.

Primary Effectiveness Endpoint: The primary effectiveness objective of the study was to demonstrate that the Vibe self-fitting (SF) strategy is non-inferior to the audiologist-fit (HCP fit) strategy in subject´s perceived hearing aid benefit after using the Vibe SF (investigational device) and Silk 1X HCP fit (comparator device) hearing aids in real-life conditions. Hearing aid benefit was measured by 3 sub-scales of the Abbreviated Profile of Hearing Aid Benefit (APHAB): ease of communication ("EC"), [ability to hear in] background noise ("BN"), and [ability to hear in] a reverberant room ("RV"). The primary endpoint result was comprised of the combined results from these subscales; success required simultaneous non-inferiority of the Vibe SF as compared to HCP fit hearing aid on all three subscales.

Primary Safety Endpoint: The safety endpoint was the rate of adverse device effects.

Patient Population: The devices were tested on 28 subjects. Table 1 shows the baseline demographics of the study subjects. All subjects reported a self-perceived hearing loss, with 71.4% describing their hearing loss with having "A little trouble" and 28.6% with having "A lot of trouble." 4 of the 28 subjects were experienced hearing aid users with a mean of 33 months of hearing aid use.

Table 1. Demographics of the study subjects

Characteristic	Summary
Gender	
Female	32.1% (9/28)
Male	67.9% (19/28)
Age Group	
25-34	3.6% (1/28)
35-44	7.1% (2/28)
45-54	14.3% (4/28)
55-64	25.0% (7/28)
65-74	28.6% (8/28)
75-84	21.4% (6/28)
Ethnicity	
Not Hispanic/Latino	100.0% (28/28)
Race	
American Indian or Alaska Native	3.6% (1/28)
American Indian or Alaska Native; Other	3.6% (1/28)
White	92.9% (26/28)

The average baseline air conduction audiograms are very similar to the results obtained in a published study with the predicate device (compare Figure 1, which shows the average air conduction audiograms of all participants of the Vibe SF study, and Figure 2 copied from Sabin et al. 2020[1]).

[1] A. V. Sabin, D. J. Van Tassel, B. Rabinowitz and S. Dhar (2020). Validation of a self-fitting method for over-the-counter hearing aids. *Trends in Hearing*, 1-19.

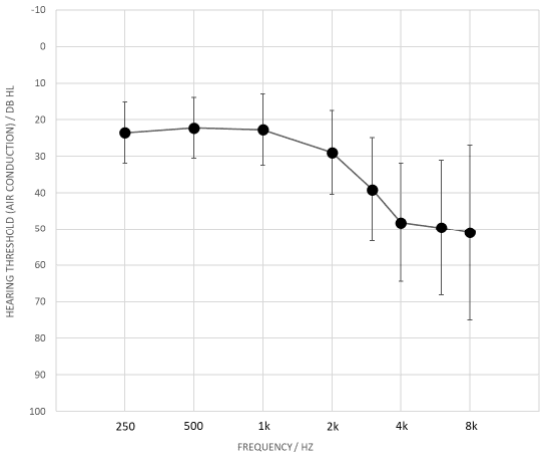

Figure 1. Average air conduction audiograms for participants in the Vibe SF Study. Error bars reflect standard deviation across all ears.

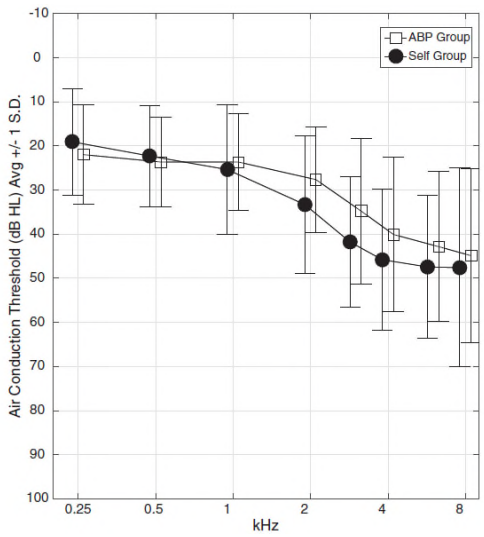

Figure 2. From Sabin et al. 2020.[1] Average air conduction audiograms for participants in the ABP (squares) and Self (circles) groups. Error bars reflect standard deviation across all ears in the group. ABP = Audiologist Best Practices.

Table 2. Patient Accountability

Stage	Investigational Device Arm Total	Control Arm Total	Total
Enrollment	28	28*	28
Treatment started	14	14	28
Treatment finished	13	13	26
Primary Safety Endpoint Analysis	28	28*	28
Primary Effectiveness Endpoint Analysis	28	28*	28**

* Cross-over design, patients are the same ones as for investigational device

** 2 subjects had missing HCP fit and Vibe data due to cause but unaided data was collected. Imputed '0' for difference of benefits for those 2 subjects for the intent to treat (ITT) summary.

Results:

The study met the primary endpoint. The primary effectiveness endpoint results demonstrated that the Vibe SF strategy is non-inferior to the HCP fit strategy in participants´ perceived hearing aid benefit. The Vibe SF strategy was non-inferior to the HCP fit strategy in each of the 3 benefit scores for each subscale in the APHAB ($p<0.001$ for each subscale/coprimary endpoint). Therefore, the Vibe SF strategy demonstrated non-inferiority to the HCP fit strategy (combined p-value <0.001).

As can be seen in Figure 3 below, there is a benefit (positive mean and median values) for both fitting strategies in all domains, suggesting that participants had fewer communication problems with the devices on average. The improvements relative to the unaided condition were significant, but the differences between the HCP fit and Vibe SF devices was not significant. For all subscales, the differences in perceived mean benefit between the two fitting strategies were very small and significantly lower than the non-inferiority margins. This means that there should be no clinical difference between the two fitting strategies.

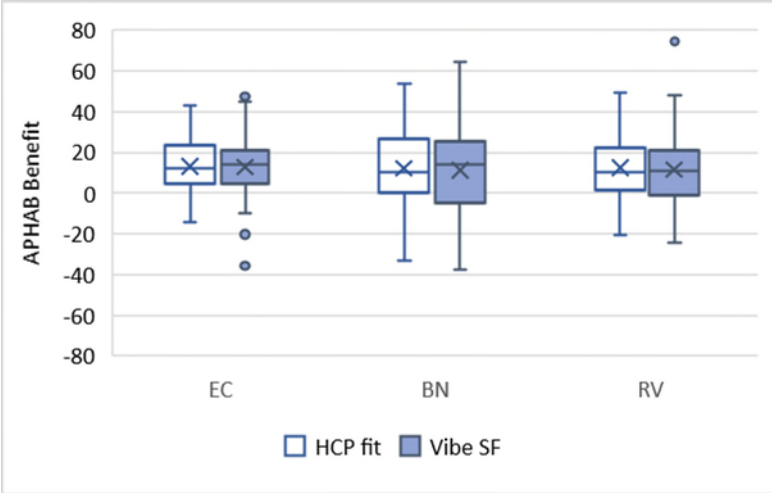

Figure 3. Results of the APHAB Benefit shown for EC, BN and RV. Boxplots show the mean, median, interquartile range and minimum/maximum. Outliers are indicated with a dot.

To be able to compare the data to the results obtained with the predicate device (Sabin et al. 2020[1]), the global APHAB scores were calculated. The comparison can be seen in Table 3 below. The baseline number of problems is slightly higher in the study population of the Vibe SF Clinical study, but the benefit with the hearing aid is very similar.

Table 3. Results of APHAB and SSQ Questionnaires, comparison to the data shown in Sabin et al. 2020[1] for the predicate device

	APHAB				SSQ	
	predicate		actual		predicate	actual
	Unaided	Benefit	Unaided	Benefit	Benefit	Benefit
HCP Fit						
Mean	31	11.94	37.53	12.63	0.91	1.03
SD	15.22	15.14	15.37	14.05	1.93	1.4
Min	12	-9	14.67	-13.11	-7.5	-2.33
Max	82	58	71.83	37.83	4.6	3.67

	APHAB				SSQ	
	predicate		actual		predicate	actual
	Unaided	Benefit	Unaided	Benefit	Benefit	Benefit
N	34	34	28	26	37	26
Self						
Mean	31.67	14.57	37.53	11.77	1.21	1.15
SD	16.02	18.31	15.37	19.26	1.7	1.63
Min	7	-27	14.67	-19.94	-1.8	-2.83
Max	67	54	71.83	61.44	5.3	3.67
N	30	30	28	26	28	26

Secondary Effectiveness Endpoint Results:

EMA Scores: Ecological Momentary Assessment (EMA) scores were similar for the self-fit strategy and HCP fit strategy in each listening situation. Both fitting strategies provided good sound quality and high speech understanding. Sound quality was rated fair to excellent in over 90% of the questionnaires. Median speech understanding was 8 or above on a scale of 0 – 10 (10 signifying “understand every word”), and satisfaction was neutral or better in over 90% of the questionnaires, with 65.5% being satisfied or very satisfied during the HCP fit trial and 75.5% being satisfied or very satisfied during the Vibe SF trial.

QuickSIN Scores: The mean and median results of the QuickSIN test for the HCP fit and for self-fit strategies were very similar, with no significant differences observed (Figure 4). With the devices, programmed to either fitting strategy, on average the participants performed in what would be considered the "normal/near normal" category for SNR-Loss (0-3 dB SNR Loss; e.g., only slightly poorer than someone with normal hearing). The QuickSIN was administered at what was considered to be an ecologically appropriate level of 50 dB HL (~62 dB SPL). At this level, slightly above average speech, we would not expect to see differences between the fitting strategies given the small differences between aided ear canal SPL, and the fact that the participants had mild-to-moderate hearing losses.

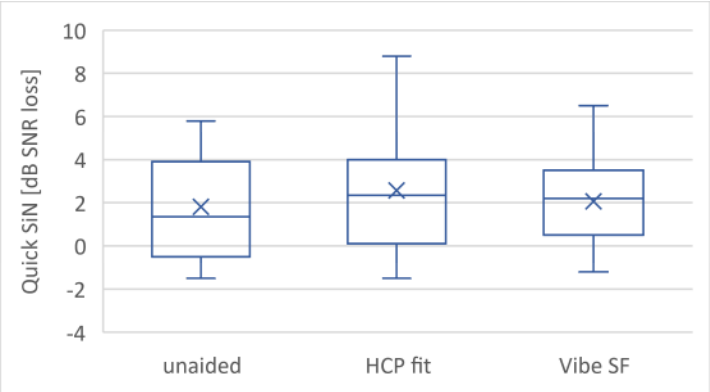

Figure 4. QuickSIN results for unaided, HCP fit and Vibe SF, speech presented at 50 dB HL. Boxplots showing the mean (“x”), median, interquartile range and minimum/maximum.

SSQ-12 Scores: In all of the aspects of hearing assessed by the SSQ-12 (domains included following speech, location and distance hearing, qualities of speech), results showed a benefit compared to unaided hearing for both fitting strategies. There was virtually no difference in

SSQ-12 scores between the HCP fit and the self-fit results. As can be seen in Table 1 (above with APHAB), SSQ-12 Benefit was also very similar to that observed with the predicate device.

Gain Selection: Real ear measurements of both the self-fit and the HCP fit devices showed similar amplification across all measured frequencies, consistent with the National Acoustic Laboratories' Nonlinear Version 2 (NAL-NL2) targets. The HCP-adjusted devices provided slightly greater amplification at higher frequencies. These results are similar to those reported for the predicate device in Sabin et al. 2020,[1] where the self-selected settings correlated with, but were lower than, the HCP-selected settings.

It is also noteworthy that the NAL-NL2 algorithm offers target calculation corrections for new users. 24 of the 28 participants in the study were new users. Several of them had hearing losses to the degree that their fitting targets would have been lowered by hearing care professionals by 2-3 dB, or maybe more. Hence, the real-life mismatch from the NAL-NL2 targets for the SF approach shown in our mean data would not be quite as large as suggested. Furthermore, the Vibe SF hearing aid does provide for user adjustments to increase or decrease gain. Most appropriate for matching to NAL-NL2 targets are adjustment options including overall master gain adjustment for the entire frequency response as well as adjustments for speech intelligibility.

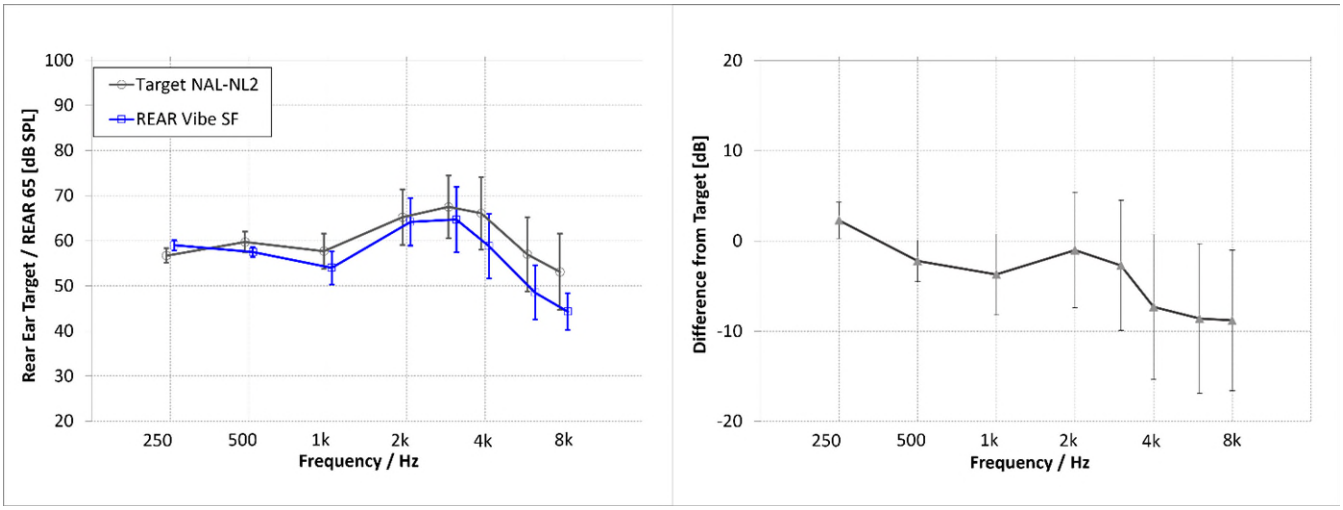

Figure 5. (Left) NAL-NL2 Target and measured REAR (real ear aided response) for medium input averaged across all subjects for Vibe SF. (Right) Average and standard deviation of the difference between NAL-NL2 target and measured responses computed across all subjects.

Fitting Preference: An equal number of participants preferred using the HCP fit hearing aids as the self-fit hearing aids (each around 40%). The remaining 20% of participants had no preference between the two fitting strategies.

Safety Outcomes: No adverse device effects were reported during the study. Two adverse events were reported which were not device or study procedure related. One event was reported as a food-related stomach issue and the other, a cold virus. Both were non-device related and resolved without medical intervention. Additionally, one use error was reported but was resolved without medical incident or untoward clinical signs; thus, it was not recorded as an adverse device effect.

Summary: This study evaluated the effectiveness of the Vibe self-fitting (SF) strategy for the Vibe SF hearing aids as measured by perceived hearing aid benefit. The data showed strong statistical evidence ($p<0.001$) that the Vibe SF strategy was non-inferior to an HCP fit strategy that used recognized prescriptive targets from the NAL-NL2. Therefore, this study demonstrates the clinical effectiveness of the Vibe SF strategy. Furthermore, the results of the primary and secondary endpoints are similar to those reported for the predicate device (ABHAB, SSQ, QuickSIN). No adverse device effects were reported during the study.

Conclusion

The Vibe SF Self-Fitting Hearing Aid is as safe and effective as the predicate Bose Hearing Aid. The Vibe SF Self-Fitting Hearing Aid has the same intended use and similar indications, technological characteristics, and principles of operation as its predicate device. In addition, the minor technological differences between the Vibe SF Self-Fitting Hearing Aid and its predicate device raise no new issues of safety or effectiveness. Thus, the Vibe SF Self-Fitting Hearing Aid is substantially equivalent.