

K220403 Vibe SF Self-Fitting Hearing AidAug 12, 2022
182 days to decisionK220403 · Product code: **QDD** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k220403/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Self-fitting Air-conduction Hearing Aid, Prescription (QDD)
Date received	Feb 11, 2022
Decision date	Aug 12, 2022
Days to decision	182 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Wsaud A/S
Location	Lyngø, DK
Contact	Kristine Klitgaard Pedersen
510(k) history	2 submissions · 2 cleared · 2022-2024

REGULATORY CONSULTANT

Consulting firm	Hogan Lovells US LLP
Contact	John Smith

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

CLINICAL EVIDENCE - NCT04972162**Fitting Strategy Study**

Status	Completed
Enrollment	28 patients (actual)
Study sites	1 site
Condition studied	Hearing Loss, Sensorineural
Primary purpose	Treatment
Study type	Interventional
Study design	Crossover
Masking	Double blind
Completion date	Nov 12, 2021
Sponsor	WSAUD A/S (Industry)

Primary outcome**Abbreviated Profile of Hearing Aid Benefit (APHAB)**Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT04972162