FDA 510(k) Premarket Notification

CLEARED

K220303 MDHearingAid app, MDHearingAid Smart hearing aids

Aug 4, 2022
183 days to decision

K220303 · Product code: **QDD** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k220303/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Self-fitting Air-conduction Hearing Aid, Prescription (QDD)
Date received	Feb 2, 2022
Decision date	Aug 4, 2022
Days to decision	183 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Mdhearingaid**
Location	Chicago, IL, US
Contact	Doug Breaker
510(k) history	1 submissions · 1 cleared · 2022-2022

CLINICAL EVIDENCE - NCT05165121

Comparison of Hearing Aid Fitting Outcomes Between Self-fit and Professional Fit for MDHearing Smart Hearing Aids

Status	Completed
Enrollment	91 patients (actual)
Study sites	1 site
Condition studied	Hearing Loss
Primary purpose	Other
Study type	Interventional
Study design	Parallel
Masking	Open label
Completion date	Sep 24, 2021
Sponsor	MDHearingAid (Industry)

Primary outcome

Number of Participants With Improvement at 1 Month as Measured by the Abbreviated Profile of Hearing Aid Benefit (APHAB) and Speech Spatial Qualities 12 (SSQ 12) Scale.

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT05165121