FDA 510(k) Premarket Notification

CLEARED

K230538 All-Day Clear Slim ADCS1 Hearing Aid. All-Day Clear ADC1 Hearing Aid

Jun 16, 2023
109 days to decision

K230538 · Product code: **QUH** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k230538/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Self-fitting Air-conduction Hearing Aid, Over The Counter (QUH)
Date received	Feb 27, 2023
Decision date	Jun 16, 2023
Days to decision	109 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Sonova AG**
Location	Zurich, CH
Contact	Nelson Hu
Website	http://www.sonova.com/
510(k) history	2 submissions · 2 cleared · 2023-2024

Sonova AG is a global hearing healthcare company headquartered in Zurich, Switzerland. The company designs and manufactures hearing aids and cochlear implant systems for patients with hearing loss. Sonova has received FDA 510(k) clearances from total submissions. The company specializes in Ear, Nose, Throat devices, which represent 100% of its FDA submissions. Recent cleared devices include the Lyric4 Hearing Aid and the All-Day Clear series. First clearance: 2023. Latest clearance: 2024. The company remains active in FDA regulatory submissions. Sonova operates a diverse ...

REGULATORY CONSULTANT

Consulting firm	**Hymann, Phelps, & Mcnamara P.C.**
Contact	Philip J.H. Won

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