

**K232999 Lyric4 Hearing Aid**Apr 11, 2024  
202 days to decisionK232999 · Product code: **ESD** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k232999/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hearing Aid, Air-conduction, Prescription (ESD)
Date received	Sep 22, 2023
Decision date	Apr 11, 2024
Days to decision	202 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

Company	<b>Sonova AG</b>
Location	Zurich, CH
Contact	Kateryna Konovalenko
Website	<a href="http://www.sonova.com/">http://www.sonova.com/</a>
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 ...

**CLINICAL EVIDENCE - NCT05349981****Lyric Self-replacement Clinical Investigation**

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	57 patients (actual)
Study sites	8 sites
Condition studied	Hearing Loss
Primary purpose	Other
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Mar 9, 2023
Sponsor	Sonova AG (Industry)

**Primary outcome**

Change in aided audiometric threshold testing between standard and experimental replacement procedures

**Secondary outcome**

Change in incidence of medical referrals secondary to device replacement procedure-related ear health outcome between standard and experimental replacement procedures

Source: ClinicalTrials.gov / U.S. National Library of Medicine - [clinicaltrials.gov/study/NCT05349981](https://clinicaltrials.gov/study/NCT05349981)