FDA 510(k) Premarket Notification

K252284 eMurmur Heart AI

CLEARED

Dec 19, 2025
150 days to decision

K252284 · Product code: **DQD** · Cardiovascular
Source: https://www.510kdatabase.net/k252284/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stethoscope, Electronic (DQD)
Date received	Jul 22, 2025
Decision date	Dec 19, 2025
Days to decision	150 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Summary

APPLICANT

Company	**Csd Labs**
Location	Graz, AT
Contact	Andreas Reinisch
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	**RQM+**
Contact	Allison C. Komiyama

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k252284/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026