

**K241142 mAXIS Stapes Prosthesis, mLOOP Stapes Prosthesis,
mZAM Stapes Prosthesis and mFIX Stapes Prosthesis**Jan 17, 2025
267 days to decisionK241142 · Product code: **ETB** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k241142/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Partial Ossicular Replacement (ETB)
Date received	Apr 25, 2024
Decision date	Jan 17, 2025
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Med-EI Elektromedizinische Ger?te GmbH
Location	Innsbruck, AT
Contact	Inés Román Santiago
510(k) history	6 submissions · 6 cleared · 2025-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k241142/> 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 13, 2026