

K241269 mXACT Total Prosthesis Offcenter, mXACT Total Prosthesis Center and mXACT PRO Total Prosthesis KitJan 17, 2025
268 days to decisionK241269 · Product code: **ETA** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k241269/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Replacement, Ossicular Prosthesis, Total (ETA)
Date received	Apr 24, 2024
Decision date	Jan 17, 2025
Days to decision	268 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

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