

K241261 mCLIP Partial Prosthesis, mCLIP ARC Partial Prosthesis, mXACT Partial Prosthesis and mXACT PRO Partial Prosthesis KitJan 17, 2025
266 days to decisionK241261 · Product code: **ETB** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k241261/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Partial Ossicular Replacement (ETB)
Date received	Apr 26, 2024
Decision date	Jan 17, 2025
Days to decision	266 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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