

K243280 Piezomed Pro (Piezomed Pro module M-PM100 incl. handpiece M-PH350, Piezomed Pro instruments (various tips) and accessories)

Jul 3, 2025
259 days to decision

K243280 · Product code: **ERL** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k243280/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drill, Surgical, Ent (electric Or Pneumatic) Including Handpiece (ERL)
Date received	Oct 17, 2024
Decision date	Jul 3, 2025
Days to decision	259 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	W&H Dentalwerk Buermoos GmbH
Location	Buermoos, AT
Contact	Gerhard Weidler
510(k) history	17 submissions · 17 cleared · 1999-2025

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k243280/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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