

**K201703 PROXEO Twist Cordless Polishing System PL-40 H**Feb 24, 2021  
247 days to decisionK201703 · Product code: **EKX** · Dental  
Source: <https://www.510kdatabase.net/k201703/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Handpiece, Direct Drive, Ac-powered (EKX)
Date received	Jun 22, 2020
Decision date	Feb 24, 2021
Days to decision	247 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>W&amp;H Dentalwerk Buermoos GmbH</b>
Location	Buermoos, AT
Contact	Johann Georg Scharl
510(k) history	17 submissions · 17 cleared · 1999-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k201703/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026