

**K213345 Sentiero, AuDX, AuDX PRO, Sentiero Desktop, AuDX PRO Flex, Sentiero Advanced, NavPRO ONE**Jun 22, 2022  
257 days to decisionK213345 · Product code: **EWO** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k213345/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Audiometer (EWO)
Date received	Oct 8, 2021
Decision date	Jun 22, 2022
Days to decision	257 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Path Medical GmbH</b>
Location	Fort Collins, CO, US
Contact	Johann Oswald
510(k) history	6 submissions · 6 cleared · 2010-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k213345/> 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 25, 2026