

K100661 EARPROBEJul 1, 2010
115 days to decisionK100661 · Product code: **GWJ** · Neurology
Source: <https://www.510kdatabase.net/k100661/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Auditory, Evoked Response (GWJ)
Date received	Mar 8, 2010
Decision date	Jul 1, 2010
Days to decision	115 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Path Medical GmbH
Location	Fort Collins, CO, US
Contact	KURT RENTEL
510(k) history	6 submissions · 6 cleared · 2010-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k100661/> Data sourced from FDA 510(k) public records (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. - Generated May 25, 2026