

K220139 QScreenAug 3, 2022
197 days to decisionK220139 · Product code: **GWJ** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k220139/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Auditory, Evoked Response (GWJ)
Date received	Jan 18, 2022
Decision date	Aug 3, 2022
Days to decision	197 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k220139/> 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