

K162037 Eclipse with VEMPMar 23, 2017
244 days to decisionK162037 · Product code: **GWJ** · Neurology
Source: <https://www.510kdatabase.net/k162037/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Auditory, Evoked Response (GWJ)
Date received	Jul 22, 2016
Decision date	Mar 23, 2017
Days to decision	244 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Interacoustics A/S
Location	Minnesota, MN, US
Contact	Erik Nielsen
510(k) history	17 submissions · 17 cleared · 2006-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k162037/> 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 June 15, 2026