

**K212325 EEG-acp**Jun 15, 2022  
324 days to decisionK212325 · Product code: **GYB** · Neurology  
Source: <https://www.510kdatabase.net/k212325/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Media, Electroconductive (GYB)
Date received	Jul 26, 2021
Decision date	Jun 15, 2022
Days to decision	324 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Somnomedics GmbH</b>
Location	Washington, DC, US
Contact	Sabrina Forster
510(k) history	7 submissions · 7 cleared · 2007-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212325/> 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 24, 2026