

**K231068 autoSCORE**Jan 7, 2024  
268 days to decisionK231068 · Product code: **OMB** · Neurology  
Source: <https://www.510kdatabase.net/k231068/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automatic Event Detection Software For Full-montage Electroencephalograph (OMB)
Date received	Apr 14, 2023
Decision date	Jan 7, 2024
Days to decision	268 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Holberg Eeg AS</b>
Location	Bergen, NO
Contact	Smriti Franklin
510(k) history	2 submissions · 2 cleared · 2024-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k231068/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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