

**K212684 BrainView QEEG Software**Jan 28, 2023  
522 days to decisionK212684 · Product code: **OLU** · Neurology  
Source: <https://www.510kdatabase.net/k212684/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Normalizing Quantitative Electroencephalograph Software (OLU)
Date received	Aug 24, 2021
Decision date	Jan 28, 2023
Days to decision	522 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medeia, Inc.</b>
Location	Miami, FL, US
Contact	Slav Danev
510(k) history	4 submissions · 4 cleared · 2015-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Compliance and Regulatory Services, LLC</b>
Contact	Daniel Lehtonen

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212684/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 27, 2026