

**K231366 Neuronaute Plus**Nov 9, 2023  
182 days to decisionK231366 · Product code: **GWQ** · Neurology  
Source: <https://www.510kdatabase.net/k231366/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Full-montage Standard Electroencephalograph (GWQ)
Date received	May 11, 2023
Decision date	Nov 9, 2023
Days to decision	182 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bioserenity Sas</b>
Location	Paris, FR
Contact	Madubuike Okafor
510(k) history	3 submissions · 3 cleared · 2018-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k231366/> 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