

**K223644 Neuronate with IceCap 2 & IceCap 2 Small**Jan 12, 2023  
37 days to decisionK223644 · Product code: **GWQ** · Neurology  
Source: <https://www.510kdatabase.net/k223644/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Full-montage Standard Electroencephalograph (GWQ)
Date received	Dec 6, 2022
Decision date	Jan 12, 2023
Days to decision	37 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bioserenity</b>
Location	Paris, FR
Contact	Madubuike Okafor
510(k) history	2 submissions · 2 cleared · 2017-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k223644/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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