

**K221963 Cumulus Functional Neurophysiology Platform**Apr 27, 2023  
296 days to decisionK221963 · Product code: **GWQ** · Neurology  
Source: <https://www.510kdatabase.net/k221963/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Full-montage Standard Electroencephalograph (GWQ)
Date received	Jul 5, 2022
Decision date	Apr 27, 2023
Days to decision	296 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cumulus Neuroscience Limited</b>
Location	Belfast, IE
Contact	Caroline Kirwan
510(k) history	1 submissions · 1 cleared · 2023-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Qserve Group, Us, Inc.</b>
Contact	Patsy J Trisler

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k221963/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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