

K230073 OktiFeb 9, 2023
30 days to decisionK230073 · Product code: **GWQ** · Neurology
Source: <https://www.510kdatabase.net/k230073/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Full-montage Standard Electroencephalograph (GWQ)
Date received	Jan 10, 2023
Decision date	Feb 9, 2023
Days to decision	30 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Compumedics Limited
Location	Minneapolis,, MN, US
Contact	John Joseph
510(k) history	9 submissions · 9 cleared · 2000-2025

REGULATORY CONSULTANT

Consulting firm	Third Party Review Group, LLC
Contact	Dave Yungvirt

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k230073/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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