

K242930 Natus BrainWatch SystemNov 19, 2024
56 days to decisionK242930 · Product code: **OMC** · Neurology
Source: <https://www.510kdatabase.net/k242930/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reduced- Montage Standard Electroencephalograph (OMC)
Date received	Sep 24, 2024
Decision date	Nov 19, 2024
Days to decision	56 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Natus Medical Incorporated Db a Excel-Tech Ltd. (Xitek)
Location	Oakville, CA
Contact	Behsa Khoshnevis
510(k) history	13 submissions · 13 cleared · 2016-2024

REGULATORY CONSULTANT

Consulting firm	Regulatory Technology Services, LLC
Contact	Prithul Bom

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

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