

K200878 Natus NeuroWorksMay 18, 2020
46 days to decisionK200878 · Product code: **OMB** · Neurology
Source: <https://www.510kdatabase.net/k200878/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automatic Event Detection Software For Full-montage Electroencephalograph (OMB)
Date received	Apr 2, 2020
Decision date	May 18, 2020
Days to decision	46 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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