

K191322 E-EEGX, N-EEGXJan 22, 2020
252 days to decisionK191322 · Product code: **OLT** · Neurology
Source: <https://www.510kdatabase.net/k191322/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Non-normalizing Quantitative Electroencephalograph Software (OLT)
Date received	May 15, 2019
Decision date	Jan 22, 2020
Days to decision	252 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	GE Healthcare Finland Oy
Location	Madison, WI, US
Contact	Joel Kent
510(k) history	30 submissions · 30 cleared · 2007-2023

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