

K192889 NeoJan 30, 2020
112 days to decisionK192889 · Product code: **OMA** · Neurology
Source: <https://www.510kdatabase.net/k192889/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Amplitude-integrated Electroencephalograph (OMA)
Date received	Oct 10, 2019
Decision date	Jan 30, 2020
Days to decision	112 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Eemagine Medical Imaging Solutions GmbH
Location	Mukwonago, WI, US
Contact	Maarten Van De Velde
510(k) history	8 submissions · 8 cleared · 2000-2024

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