

K211452 EncevisDec 2, 2021
206 days to decisionK211452 · Product code: **OMB** · Neurology
Source: <https://www.510kdatabase.net/k211452/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automatic Event Detection Software For Full-montage Electroencephalograph (OMB)
Date received	May 10, 2021
Decision date	Dec 2, 2021
Days to decision	206 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Austrian Institute of Technology GmbH
Location	Vienna, AT
Contact	Tilmann Kluge
510(k) history	1 submissions · 1 cleared · 2021-2021

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211452/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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