

K240993 encevis (2.1)Sep 27, 2024
169 days to decisionK240993 · Product code: **OMB** · Neurology
Source: <https://www.510kdatabase.net/k240993/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automatic Event Detection Software For Full-montage Electroencephalograph (OMB)
Date received	Apr 11, 2024
Decision date	Sep 27, 2024
Days to decision	169 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ait Austrian Institute of Technology GmbH
Location	Vienna, AT
Contact	Tilmann Kluge
510(k) history	2 submissions · 2 cleared · 2018-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k240993/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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