

K183529 AE-120A EEG Head SetMar 19, 2019
90 days to decisionK183529 · Product code: **OMC** · Neurology
Source: <https://www.510kdatabase.net/k183529/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reduced- Montage Standard Electroencephalograph (OMC)
Date received	Dec 19, 2018
Decision date	Mar 19, 2019
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Nihon Kohden Corporation
Location	Tokyo, JP
Contact	Tom Bento
510(k) history	18 submissions · 18 cleared · 2015-2025

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