

**K251366 EEG-1260A Neurofax System (EEG-1260A)**Oct 9, 2025  
161 days to decisionK251366 · Product code: **OLT** · Neurology  
Source: <https://www.510kdatabase.net/k251366/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Non-normalizing Quantitative Electroencephalograph Software (OLT)
Date received	May 1, 2025
Decision date	Oct 9, 2025
Days to decision	161 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	JE-940A EEG Amplifier Unit (JE-940A); LS-940A Photic Stimulator (LS-940A)

**APPLICANT**

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Company	<b>Nihon Kohden Corporation</b>
Location	Tokyo, JP
Contact	Sandra Gadeyne
510(k) history	18 submissions · 18 cleared · 2015-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Nihon Kohden America, LLC</b>
Contact	Charlemagne Chua

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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