

K130238 NIHON KOHDEN AE-918P NEURO UNITMar 4, 2015
762 days to decisionK130238 · Product code: **OMA** · Neurology
Source: <https://www.510kdatabase.net/k130238/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Amplitude-integrated Electroencephalograph (OMA)
Date received	Jan 31, 2013
Decision date	Mar 4, 2015
Days to decision	762 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Nihon Kohden Corp.
Location	Foothill, CA, US
Contact	NATALIE KENNEL
510(k) history	9 submissions · 9 cleared · 2010-2015

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