FDA 510(k) Premarket Notification

K000338 VITAPORT 3

CLEARED

Apr 26, 2000
83 days to decision

K000338 · Product code: **OLV** · Neurology
Source: https://www.510kdatabase.net/k000338/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Standard Polysomnograph With Electroencephalograph (OLV)
Date received	Feb 3, 2000
Decision date	Apr 26, 2000
Days to decision	83 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Nihon Kohden America, Inc.**
Location	Foothill Ranch, CA, US
Contact	BONNIE BISHOP
510(k) history	166 submissions · 163 cleared · 1979-2012