FDA 510(k) Premarket Notification

K983072 AMBULATORY EEG/SLEEP RECORDER AND ACCESSORIES, MODEL # SSR3201

CLEARED

Dec 1, 1998
90 days to decision

K983072 · Product code: **OLV** · Neurology
Source: https://www.510kdatabase.net/k983072/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Standard Polysomnograph With Electroencephalograph (OLV)
Date received	Sep 2, 1998
Decision date	Dec 1, 1998
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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