FDA 510(k) Premarket Notification

K001433 CNS-9300 SERIES CENTRAL STATION

CLEARED

Nov 7, 2000
183 days to decision

K001433 · Product code: **MHX** · Cardiovascular
Source: https://www.510kdatabase.net/k001433/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	May 8, 2000
Decision date	Nov 7, 2000
Days to decision	183 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