FDA 510(k) Premarket Notification

CLEARED

K190468 Nihon Kohden SVM-7200 Series Vital Signs Monitor

May 28, 2019
91 days to decision

K190468 · Product code: **MWI** · Cardiovascular
Source: https://www.510kdatabase.net/k190468/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Feb 26, 2019
Decision date	May 28, 2019
Days to decision	91 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**Nihon Kohden Corporation**
Location	Tokyo, JP
Contact	Thomas Bento
510(k) history	18 submissions · 18 cleared · 2015-2025