

K192307 Nihon Kohden NKV-550 Series Ventilator SystemJan 10, 2020
137 days to decisionK192307 · Product code: **CBK** · Anesthesiology
Source: <https://www.510kdatabase.net/k192307/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Continuous, Facility Use (CBK)
Date received	Aug 26, 2019
Decision date	Jan 10, 2020
Days to decision	137 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Nihon Kohden Oranemed, Inc.
Location	Santa Ana, CA, US
Contact	Sheryl Higgins
510(k) history	4 submissions · 4 cleared · 2018-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k192307/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 27, 2026