

K222644 Nihon Kohden NKV-440 Ventilator SystemMay 31, 2023
272 days to decisionK222644 · Product code: **CBK** · Anesthesiology
Source: <https://www.510kdatabase.net/k222644/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Continuous, Facility Use (CBK)
Date received	Sep 1, 2022
Decision date	May 31, 2023
Days to decision	272 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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