

**K231778 Nihon Kohden NKV-550 Series Ventilator System**Mar 1, 2024  
259 days to decisionK231778 · Product code: **CBK** · Anesthesiology  
Source: <https://www.510kdatabase.net/k231778/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Continuous, Facility Use (CBK)
Date received	Jun 16, 2023
Decision date	Mar 1, 2024
Days to decision	259 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Nihon Kohden Oranemed, LLC</b>
Location	Santa Ana, CA, US
Contact	Sheryl Higgins
510(k) history	1 submissions · 1 cleared · 2024-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k231778/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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