

**K213521 Nihon Kohden NKV-330 Ventilator System**Jul 1, 2022  
240 days to decisionK213521 · Product code: **MNT** · Anesthesiology  
Source: <https://www.510kdatabase.net/k213521/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Continuous, Minimal Ventilatory Support, Facility Use (MNT)
Date received	Nov 3, 2021
Decision date	Jul 1, 2022
Days to decision	240 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Nihon Kohden Oranemed, Inc.</b>
Location	Santa Ana, CA, US
Contact	Jacqueline Villanueva
510(k) history	4 submissions · 4 cleared · 2018-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k213521/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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