

**K181695 Nihon Kohden NKV-550 Series Ventilator System**Dec 7, 2018  
163 days to decisionK181695 · Product code: **CBK** · Anesthesiology  
Source: <https://www.510kdatabase.net/k181695/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Continuous, Facility Use (CBK)
Date received	Jun 27, 2018
Decision date	Dec 7, 2018
Days to decision	163 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Nihon Kohden Oranemed, Inc.</b>
Location	Santa Ana, CA, US
Contact	Sheryl Higgins
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/k181695/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 27, 2026