

**K203435 Nihon Kohden Life Scope G5 Bedside Monitoring System, Nihon Kohden Life Scope G7 Bedside Monitoring System**Jul 16, 2021  
235 days to decisionK203435 · Product code: **MHX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k203435/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Nov 23, 2020
Decision date	Jul 16, 2021
Days to decision	235 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Nihon Kohden Corporation</b>
Location	Tokyo, JP
Contact	Sandra Gadeyne
510(k) history	18 submissions · 18 cleared · 2015-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Nihon Kohden America</b>
Contact	Sandra Gadeyne

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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**510k Database** - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k203435/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 24, 2026