FDA 510(k) Premarket Notification

CLEARED

K203435 Nihon Kohden Life Scope G5 Bedside Monitoring System, Nihon Kohden Life Scope G7 Bedside Monitoring System

Jul 16, 2021
235 days to decision

K203435 · Product code: **MHX** · Cardiovascular
Source: https://www.510kdatabase.net/k203435/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**Nihon Kohden America**
Contact	Sandra Gadeyne

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