FDA 510(k) Premarket Notification

K223567 CNS-2101 Central Monitor

CLEARED

Jul 31, 2023
244 days to decision

K223567 · Product code: **MSX** · Cardiovascular
Source: https://www.510kdatabase.net/k223567/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Network And Communication, Physiological Monitors (MSX)
Date received	Nov 29, 2022
Decision date	Jul 31, 2023
Days to decision	244 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