CLEARED

Dec 29, 2021
86 days to decision

K213316 Life Scope PT BSM-1700 Series, AY Series, Data Acquisition Unit, LIFE SCOPE BSM 6000 SERIES BEDSIDE MONITORING SYSTEM, Nihon Kohden CSM-1901 BEDSIDE MONITORING SYSTEM

K213316 · Product code: **KOI** · Anesthesiology
Source: https://www.510kdatabase.net/k213316/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Stimulator, Nerve, Peripheral, Electric (KOI)
Date received	Oct 4, 2021
Decision date	Dec 29, 2021
Days to decision	86 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, Inc.**
Contact	Sunita Teekasingh

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