

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 SYSTEMDec 29, 2021
86 days to decisionK213316 · 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

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