FDA 510(k) Premarket Notification

CLEARED

K201949 Smart Cable NMT Module and Accessories, Life Scope BSM 3000 Series and Life Scope BSM 6000 Series

May 2, 2021
293 days to decision

K201949 · Product code: **KOI** · Anesthesiology
Source: https://www.510kdatabase.net/k201949/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Peripheral, Electric (KOI)
Date received	Jul 13, 2020
Decision date	May 2, 2021
Days to decision	293 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