FDA 510(k) Premarket Notification

K220976 Life Scope PT BSM-1700 Series Bedside Monitor

CLEARED

Jul 21, 2022
108 days to decision

K220976 · Product code: **KOI** · Anesthesiology
Source: https://www.510kdatabase.net/k220976/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Stimulator, Nerve, Peripheral, Electric (KOI)
Date received	Apr 4, 2022
Decision date	Jul 21, 2022
Days to decision	108 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 Koden America, Inc.**
Contact	Sunita Teekasingh

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