FDA 510(k) Premarket Notification

K231064 ReddyPort Elbow

CLEARED

Jul 13, 2023
90 days to decision

K231064 · Product code: **MNS** · Anesthesiology
Source: https://www.510kdatabase.net/k231064/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Continuous, Non-life-supporting (MNS)
Date received	Apr 14, 2023
Decision date	Jul 13, 2023
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Smd Manufacturing, LLC**
Location	Salt Lake City, UT, US
Contact	Jared Spendlove
510(k) history	2 submissions · 2 cleared · 2018-2023

REGULATORY CONSULTANT

Consulting firm	**leanRAQA, LLC**
Contact	Tianna Benson

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