FDA 510(k) Premarket Notification

CLEARED

K221634 Oxymag - Transport and Emergency Ventilator

May 24, 2023
352 days to decision

K221634 · Product code: **BTL** · Anesthesiology
Source: https://www.510kdatabase.net/k221634/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Emergency, Powered (resuscitator) (BTL)
Date received	Jun 6, 2022
Decision date	May 24, 2023
Days to decision	352 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Magnamed Tecnologia Medica S/A**
Location	Cotia, BR
Contact	Toru Kinjo
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**Magnamed USA**
Contact	Claudio Cesar Bacelar

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