

K221634 Oxymag - Transport and Emergency VentilatorMay 24, 2023
352 days to decisionK221634 · 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](https://accessdata.fda.gov)

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k221634/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026