FDA 510(k) Premarket Notification

K221841 EOlife®

CLEARED

Mar 18, 2023
267 days to decision

K221841 · Product code: **BTM** · Anesthesiology
Source: https://www.510kdatabase.net/k221841/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Emergency, Manual (resuscitator) (BTM)
Date received	Jun 24, 2022
Decision date	Mar 18, 2023
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Archeon**
Location	Besan?on, FR
Contact	Valentine OQDA
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**Gloster Biomedical International, LLC**
Contact	Catherine Gloster

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