

**K221841 EOLife®**Mar 18, 2023  
267 days to decisionK221841 · Product code: **BTM** · Anesthesiology  
Source: <https://www.510kdatabase.net/k221841/>**SUBMISSION DETAILS**

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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**

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Company	<b>Archeon</b>
Location	Besançon, FR
Contact	Valentine QQDA
510(k) history	1 submissions · 1 cleared · 2023-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Gloster Biomedical International, LLC</b>
Contact	Catherine Gloster

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k221841/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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