

**K210288 Disposable Manual Resuscitator**Aug 26, 2021  
205 days to decisionK210288 · Product code: **BTM** · Anesthesiology  
Source: <https://www.510kdatabase.net/k210288/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Emergency, Manual (resuscitator) (BTM)
Date received	Feb 2, 2021
Decision date	Aug 26, 2021
Days to decision	205 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Xiamen Compower Medical Tech. Co., Ltd.</b>
Location	Xiamen, CN
Contact	Lifen Chen
510(k) history	2 submissions · 2 cleared · 2017-2021

**REGULATORY CONSULTANT**

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Consulting firm	<b>Zi-medical, Inc.</b>
Contact	Mingzi Hussey

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

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