

**K192971 Nebulizer Kit**Jul 8, 2021  
624 days to decisionK192971 · Product code: **CAF** · Anesthesiology  
Source: <https://www.510kdatabase.net/k192971/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nebulizer (direct Patient Interface) (CAF)
Date received	Oct 23, 2019
Decision date	Jul 8, 2021
Days to decision	624 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Excellentcare Medical (Huizhou) , Ltd.</b>
Location	Huizhou, CN
Contact	Chunyu Zhao
510(k) history	1 submissions · 1 cleared · 2021-2021

**REGULATORY CONSULTANT**

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Consulting firm	<b>Shenzhen Joyantech Consulting Co., Ltd.</b>
Contact	Elly Xu

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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