

**K201397 Ultrasonic Mesh Nebulizer**Jun 14, 2021  
382 days to decisionK201397 · Product code: **CAF** · Anesthesiology  
Source: <https://www.510kdatabase.net/k201397/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nebulizer (direct Patient Interface) (CAF)
Date received	May 28, 2020
Decision date	Jun 14, 2021
Days to decision	382 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Shenzhen Ivankaca Technology Co., Ltd.</b>
Location	Shenzhen, CN
Contact	Sam Wong
510(k) history	1 submissions · 1 cleared · 2021-2021

**REGULATORY CONSULTANT**

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Consulting firm	<b>Shenzhen Hlongmed Biotech Co., Ltd.</b>
Contact	Long Yang

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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