

K212395 NebulizerMar 25, 2022
235 days to decisionK212395 · Product code: **CAF** · Anesthesiology
Source: <https://www.510kdatabase.net/k212395/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nebulizer (direct Patient Interface) (CAF)
Date received	Aug 2, 2021
Decision date	Mar 25, 2022
Days to decision	235 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shenzhen Homed Medical Device Co., Ltd.
Location	Shenzhen, CN
Contact	Shi Shengming
510(k) history	4 submissions · 4 cleared · 2017-2025

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