

**K251888 VPAP Pediatric Face Mask**Mar 12, 2026  
265 days to decisionK251888 · Product code: **CBK** · Anesthesiology  
Source: <https://www.510kdatabase.net/k251888/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Continuous, Facility Use (CBK)
Date received	Jun 20, 2025
Decision date	Mar 12, 2026
Days to decision	265 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hsiner Co., Ltd.</b>
Location	Taichung City, TW
Contact	Sandy Chang
510(k) history	7 submissions · 7 cleared · 2005-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Voler Biotech Consulting CO., Ltd.</b>
Contact	Yvonne Chen

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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