

**K210878 Surgical Face Mask (Model: CM2006, CM2008, A88)**Sep 28, 2021  
188 days to decisionK210878 · Product code: **FXX** · General Hospital  
Source: <https://www.510kdatabase.net/k210878/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Mar 24, 2021
Decision date	Sep 28, 2021
Days to decision	188 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Shenzhen Realtone Medical Appliance Co., Ltd.</b>
Location	Shenzhen, CN
Contact	Wei Zhou
510(k) history	1 submissions · 1 cleared · 2021-2021

**REGULATORY CONSULTANT**

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Consulting firm	<b>Feiyang Drug &amp; Medical Consulting Technical Service Group</b>
Contact	Tracy Che

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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