

K203704 Surgical face maskJun 4, 2021
168 days to decisionK203704 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k203704/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Dec 18, 2020
Decision date	Jun 4, 2021
Days to decision	168 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Juntech(Jiaxing)Healthcare Materials Co.,Ltd
Location	Jiaxing, CN
Contact	Cam Sun
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Feiyang Drug & Medical Consulting Technical Service Group
Contact	Gamma Zhang

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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