

K202126 Disposable Surgical MaskJun 8, 2021
312 days to decisionK202126 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k202126/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Jul 31, 2020
Decision date	Jun 8, 2021
Days to decision	312 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shenzhen Peninsula Medical Co., Ltd.
Location	Shenzhen, CN
Contact	Zhang Sudi
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Share Info (Guangzhou) Medical Consultant , Ltd.
Contact	Cassie Lee

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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