

K201974 Single-use medical face maskMar 7, 2021
235 days to decisionK201974 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k201974/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Jul 15, 2020
Decision date	Mar 7, 2021
Days to decision	235 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Guangdong Horigen Mother & Baby Products Co., Ltd.
Location	Shantou, CN
Contact	Jun Deng
510(k) history	6 submissions · 6 cleared · 2016-2022

REGULATORY CONSULTANT

Consulting firm	Guangzhou Osmunda Medical Device Technical Service Co., Ltd.
Contact	Olivia Meng

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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