FDA 510(k) Premarket Notification

K201974 Single-use medical face mask

CLEARED

Mar 7, 2021
235 days to decision

K201974 · 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