

K202316 Medical mask (Model: KKF-1A)Mar 3, 2021
198 days to decisionK202316 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k202316/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Aug 17, 2020
Decision date	Mar 3, 2021
Days to decision	198 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Han Zhaoqing Sporting Goods Company Limited
Location	Zhaoqing, CN
Contact	Zhang Ming
510(k) history	2 submissions · 2 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

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