

K203534 Surgical face mask (Model: Flat Ear Loop/CN102)Jul 21, 2021
231 days to decisionK203534 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k203534/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Dec 2, 2020
Decision date	Jul 21, 2021
Days to decision	231 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Crown Name Disposable Hygiene Products Fty., Ltd.
Location	Wuhan, CN
Contact	Ying Fang
510(k) history	2 submissions · 2 cleared · 2021-2022

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