

K203161 Surgical Face MaskJan 20, 2022
454 days to decisionK203161 · Product code: **FXX** · General HospitalSource: <https://www.510kdatabase.net/k203161/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Oct 23, 2020
Decision date	Jan 20, 2022
Days to decision	454 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Wuhan Raytex Protection Co., Ltd.
Location	Wuhan, CN
Contact	Maggie Yao
510(k) history	1 submissions · 1 cleared · 2022-2022

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