

K203524 Surgical MasksFeb 25, 2021
86 days to decisionK203524 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k203524/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Dec 1, 2020
Decision date	Feb 25, 2021
Days to decision	86 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Bain Medical Equipment (Guangzhou) Co., Ltd.
Location	Guangzhou, CN
Contact	Mu Fanzhen
510(k) history	6 submissions · 6 cleared · 2017-2024

REGULATORY CONSULTANT

Consulting firm	Mid-Link Consulting Co, Ltd.
Contact	Diana Hong

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k203524/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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