

K200923 Single-use Surgical MaskAug 26, 2020
141 days to decisionK200923 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k200923/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Apr 7, 2020
Decision date	Aug 26, 2020
Days to decision	141 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Byd Precision Manufacturer Co., Ltd.
Location	Shenzhen, CN
Contact	Yubo Guan
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	Nova Clinical Solutions, Inc.
Contact	Annie Zhang

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

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