

**K210970 Single-Use Surgical Mask Model FE2311B**Jul 21, 2021  
112 days to decisionK210970 · Product code: **FXX** · General Hospital  
Source: <https://www.510kdatabase.net/k210970/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Mar 31, 2021
Decision date	Jul 21, 2021
Days to decision	112 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Byd Precison Manufacturer Co., Ltd.</b>
Location	Shenzhen, CN
Contact	Yubo Guan
510(k) history	1 submissions · 1 cleared · 2021-2021

**REGULATORY CONSULTANT**

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Consulting firm	<b>Global Healthcare Product Solutions, LLC</b>
Contact	Jenny Jing

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k210970/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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