

**K201893 Disposable Surgical Mask**Dec 9, 2020  
154 days to decisionK201893 · Product code: **FXX** · General Hospital  
Source: <https://www.510kdatabase.net/k201893/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Jul 8, 2020
Decision date	Dec 9, 2020
Days to decision	154 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Xiamen Probtain Medical Technology Co., Ltd.</b>
Location	Xiamen, CN
Contact	MR./MRS. Kangjianli
510(k) history	4 submissions · 4 cleared · 2020-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k201893/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 26, 2026