

**K201868 Phyziofit Medical Surgical Mask**Feb 22, 2021  
230 days to decisionK201868 · Product code: **FXX** · General Hospital  
Source: <https://www.510kdatabase.net/k201868/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Jul 7, 2020
Decision date	Feb 22, 2021
Days to decision	230 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Wellpower Sporting Goods Co., Ltd.</b>
Location	Dongguan, CN
Contact	Carol Tseng
510(k) history	1 submissions · 1 cleared · 2021-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k201868/> 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 27, 2026