

**K201537 Protective Face Mask for Medical Use**Sep 4, 2020  
88 days to decisionK201537 · Product code: **FXX** · General Hospital  
Source: <https://www.510kdatabase.net/k201537/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Jun 8, 2020
Decision date	Sep 4, 2020
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Shandong Shengquan New Material Co., Ltd.</b>
Location	Jinan, CN
Contact	Xiumei Zhang
510(k) history	3 submissions · 3 cleared · 2020-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k201537/> 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