

**K153496 Disposable Surgical Face Mask**Jun 15, 2016  
191 days to decisionK153496 · Product code: **FXX** · General Hospital  
Source: <https://www.510kdatabase.net/k153496/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Dec 7, 2015
Decision date	Jun 15, 2016
Days to decision	191 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Xiantao Rayxin Medical Products Co., Ltd.</b>
Location	Xiantao, CN
Contact	Liang Zhang
510(k) history	3 submissions · 3 cleared · 2016-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k153496/> 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