

**K111559 SURGICAL MASKS**Sep 16, 2011  
102 days to decisionK111559 · Product code: **FXX** · General Hospital  
Source: <https://www.510kdatabase.net/k111559/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Jun 6, 2011
Decision date	Sep 16, 2011
Days to decision	102 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Shanghai Neo-Medical Import &amp; Export Co., Ltd.</b>
Location	Shanghai, CN
Contact	Diana Hong
510(k) history	1 submissions · 1 cleared · 2011-2011

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k111559/> 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 June 18, 2026