

**K043199 SURGICAL FACE MASK**Feb 16, 2005  
90 days to decisionK043199 · Product code: **FXX** · General HospitalSource: <https://www.510kdatabase.net/k043199/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Nov 18, 2004
Decision date	Feb 16, 2005
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hong YA Non-Woven Products Co., Ltd.</b>
Location	Chino, CA, US
Contact	JAMES CHU
510(k) history	2 submissions · 2 cleared · 2005-2006

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k043199/> 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 30, 2026