

**K984389 TOP WHOLESOME FACE MASK**Apr 9, 1999  
122 days to decisionK984389 · Product code: **FXX** · General Hospital  
Source: <https://www.510kdatabase.net/k984389/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Dec 8, 1998
Decision date	Apr 9, 1999
Days to decision	122 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Top Wholesome Enterprise Co., Ltd.</b>
Location	Bangna, TH
Contact	URAI CHAROENSUK
510(k) history	1 submissions · 1 cleared · 1999-1999

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k984389/> 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 July 4, 2026