

**K063334 SHANGHAI GANGHAI MODEL GIKO 1400**Dec 8, 2006  
32 days to decisionK063334 · Product code: **MSH** · General Hospital  
Source: <https://www.510kdatabase.net/k063334/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Respirator, Surgical (MSH)
Date received	Nov 6, 2006
Decision date	Dec 8, 2006
Days to decision	32 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Shanghai Gangkai Purifying Products Co., Ltd.</b>
Location	Vero Beach, FL, US
Contact	JOSEPH Z ZDROK
510(k) history	1 submissions · 1 cleared · 2006-2006

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k063334/> 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 29, 2026