

**K133070 SURGICAL FACE MASK (Ear Loops and Tie-on)**Jun 22, 2015  
630 days to decisionK133070 · Product code: **FXX** · General HospitalSource: <https://www.510kdatabase.net/k133070/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Sep 30, 2013
Decision date	Jun 22, 2015
Days to decision	630 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bh Medical Products Co., Ltd.</b>
Location	Dover, DE, US
Contact	LEON LU
510(k) history	3 submissions · 3 cleared · 2015-2019

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k133070/> 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 28, 2026