

**K201698 Medical Surgical Mask**Mar 15, 2021  
266 days to decisionK201698 · Product code: **FXX** · General Hospital  
Source: <https://www.510kdatabase.net/k201698/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Jun 22, 2020
Decision date	Mar 15, 2021
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hangzhou Mycode Bio-Medicine Co., Ltd.</b>
Location	Hangzhou, CN
Contact	Alice Gong
510(k) history	1 submissions · 1 cleared · 2021-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k201698/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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