

**K202598 3 Layer Surgical Mask with Ear Loops Level 1, 3 Layer Surgical Mask with Ties Level 1, 3 Layer Surgical Mask with Ear Loops Level 2, 3 Layer Surgical Mask with Ties Level 2, 3 Layer Surgical Mask with Ear Loops Level 3, 3 Layer Surgical Marks with Ties Level 3**May 6, 2021  
240 days to decisionK202598 · Product code: FXX · General Hospital  
Source: <https://www.510kdatabase.net/k202598/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Sep 8, 2020
Decision date	May 6, 2021
Days to decision	240 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>3A Medical Products Co., Ltd.</b>
Location	Liu An, CN
Contact	Slinda Ma
510(k) history	2 submissions · 2 cleared · 2021-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k202598/> 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 May 27, 2026