

**K242502 Aurelia Surgical Mask ASTM Level-3 (2130)**Nov 12, 2024  
82 days to decisionK242502 · Product code: **FXX** · General Hospital  
Source: <https://www.510kdatabase.net/k242502/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Aug 22, 2024
Decision date	Nov 12, 2024
Days to decision	82 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Supermax Healthcare Canada-Supermax Medical</b>
Location	Saint-Bruno-De-Montarville, CA
Contact	Chiew Yi Tay
510(k) history	2 submissions · 2 cleared · 2023-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>Maxter Healthcare, Inc.</b>
Contact	Sajeev Joseph

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)**510k Database** - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k242502/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 13, 2026