

**K231005 Aurelia Surgical Mask ASTM Level 1**Dec 5, 2023  
242 days to decisionK231005 · Product code: **FXX** · General Hospital  
Source: <https://www.510kdatabase.net/k231005/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Apr 7, 2023
Decision date	Dec 5, 2023
Days to decision	242 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Aurelia Surgical Mask ASTM Level 2

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Dicentra, Inc.</b>
Contact	Alicja Wojewnik

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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