

K230383 Savvy Surgical Mask - Level 3Mar 6, 2023
21 days to decisionK230383 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k230383/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Feb 13, 2023
Decision date	Mar 6, 2023
Days to decision	21 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Alg Health, LLC
Location	Bryan, OH, US
Contact	Doug Soper
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	Regulatory Technology Services, LLC
Contact	Prithul Bom

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.netDevice record: <https://www.510kdatabase.net/k230383/> Data sourced from FDA 510(k) public records (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. - Generated May 27, 2026