

**K252941 HALYARD* Adult Face Mask with SO SOFT* Lining
and SO SOFT* Earloops**Dec 11, 2025
87 days to decisionK252941 · Product code: FXX · General Hospital
Source: <https://www.510kdatabase.net/k252941/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Sep 15, 2025
Decision date	Dec 11, 2025
Days to decision	87 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	O&M Halyard, Inc.
Location	Alpharetta, GA, US
Contact	Anureet Singh
510(k) history	23 submissions · 23 cleared · 2019-2026

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