

K232894 HALYARD* FLUIDSHIELD* 2 Surgical Mask with Expanded Chamber with SO SOFT* Lining (39123), HALYARD* FLUIDSHIELD* 2 Surgical Mask with Expanded Chamber with SO SOFT* Lining and Visor (39124)

Jan 8, 2024
112 days to decision

K232894 · Product code: FXX · General Hospital
Source: <https://www.510kdatabase.net/k232894/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Sep 18, 2023
Decision date	Jan 8, 2024
Days to decision	112 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Owens & Minor (O&M) Halyard, Inc.
Location	Mechanicsville, VA, US
Contact	Anureet Singh
510(k) history	12 submissions · 12 cleared · 2019-2025

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k232894/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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