

K232777 FLUIDSHIELD* 1 Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops, Lavender (25868)Jul 1, 2024
294 days to decisionK232777 · Product code: FXX · General Hospital
Source: <https://www.510kdatabase.net/k232777/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Sep 11, 2023
Decision date	Jul 1, 2024
Days to decision	294 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	FLUIDSHIELD* 1 FogFree Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops, Lavender, Wrap Around Visor (41798)

APPLICANT

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

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