

K232812 Fluidshield* 2 Fog-Free Surgical Mask (62113)Jun 14, 2024
276 days to decisionK232812 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k232812/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Sep 12, 2023
Decision date	Jun 14, 2024
Days to decision	276 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Fluidshield* 2 Fog-Free Surgical Mask with Wraparound Visor (62114); Fluidshield* 2 Procedure Mask with SO SOFT* Earloops (62115); Fluidshield* 2 Procedure Mask with SO SOFT* Earloops and WrapAround Visor (62116)

APPLICANT

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

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