

K243010 Fluidshield * 3 Fog-Free Surgical Mask with Wraparound Anti-Glare Visor (28804)

May 30, 2025
246 days to decision

K243010 · Product code: FXX · General Hospital
Source: <https://www.510kdatabase.net/k243010/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Mask, Surgical (FXX)
Date received	Sep 26, 2024
Decision date	May 30, 2025
Days to decision	246 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Fluidshield * 3 Surgical Mask with SO SOFT* Lining (48208); Fluidshield * 3 Fog-Free Surgical Mask with SO SOFT* Lining (48207); Fluidshield * 3 Fog-Free Surgical Mask with SO SOFT* Lining, with Visor (48237); Fluidshield* 3 Fog-Free Surgical Mask with SO SOFT* Lining, Anti-Glare WrapAround Visor (48247); Fluidshield * 3 Fog-Free Procedure Mask with SO SOFT* Earloops (28797); Fluidshield * 3 Fog-Free Proce

APPLICANT

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