

K232807 Fluidshield* 1 Procedure Mask with SO SOFT* Lining and SO SOFT Earloops (25869)

Jun 21, 2024
283 days to decision

K232807 · Product code: FXX · General Hospital
Source: <https://www.510kdatabase.net/k232807/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Sep 12, 2023
Decision date	Jun 21, 2024
Days to decision	283 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Fluidshield* 1 Surgical Mask with SO SOFT* Lining (28802)

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
