

**K232824 FLUIDSHIELD\* 1 Fog-Free Procedure Mask with SO SOFT\* Lining and SO SOFT\* Earloops, White (41802)**

Jul 2, 2024  
293 days to decision

K232824 · Product code: FXX · General Hospital  
Source: <https://www.510kdatabase.net/k232824/>

**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Sep 13, 2023
Decision date	Jul 2, 2024
Days to decision	293 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	FLUIDSHIELD* 1 Fog-Free Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops, White, Wrap Around Visor (41803); FLUIDSHIELD* 1 Surgical Mask with SO SOFT* Lining, White, (41805)

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k232824/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 14, 2026