

**K232820 HALYARD* FLUIDSHIELD* 1 Fog-Free Surgical Mask
with So Soft Lining (28806)**Jun 4, 2024
265 days to decisionK232820 · Product code: FXX · General Hospital
Source: <https://www.510kdatabase.net/k232820/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Mask, Surgical (FXX) |
| Date received | Sep 13, 2023 |
| Decision date | Jun 4, 2024 |
| Days to decision | 265 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k232820/> Data sourced from FDA 510(k) public records (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. - Generated May 13, 2026