

**K232806 HALYARD\* FLUIDSHIELD\* 1 Procedure Mask with So Soft Lining and So Soft Earloops (25867)**Jun 7, 2024  
269 days to decisionK232806 · Product code: FXX · General Hospital  
Source: <https://www.510kdatabase.net/k232806/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Sep 12, 2023
Decision date	Jun 7, 2024
Days to decision	269 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	HALYARD* Level 1 Procedure Mask (48388)

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k232806/> 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