

**K251967 HALYARD\* FLUIDSHIELD\* 3 Fog-Free Procedure Mask with SO SOFT\* Lining and SO SOFT\* Earloops**

Mar 18, 2026  
265 days to decision

K251967 · Product code: FXX · General Hospital  
Source: <https://www.510kdatabase.net/k251967/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Jun 26, 2025
Decision date	Mar 18, 2026
Days to decision	265 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	HALYARD* FLUIDSHIELD* 3 Fog-Free Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops with WrapAround Visor

**APPLICANT**

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Company	<b>O&amp;M Halyard, Inc.</b>
Location	Alpharetta, GA, US
Contact	Anureet Singh
510(k) history	23 submissions · 23 cleared · 2019-2026

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