

K143287 Fluidshield* Surgical Mask with Expanded ChamberMar 24, 2015
127 days to decisionK143287 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k143287/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Mask, Surgical (FXX)
Date received	Nov 17, 2014
Decision date	Mar 24, 2015
Days to decision	127 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Halyard Health, Inc.
Location	Roswell, GA, US
Contact	Roberto F. Refeca
510(k) history	7 submissions · 6 cleared · 2015-2018

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