

**K153255 Aero Chrome\* Breathable Performance Surgical Gown**Apr 13, 2016  
155 days to decisionK153255 · Product code: **FYA** · General Hospital  
Source: <https://www.510kdatabase.net/k153255/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Nov 10, 2015
Decision date	Apr 13, 2016
Days to decision	155 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Halyard Health, Inc.</b>
Location	Roswell, GA, US
Contact	DAVID M. LEE
510(k) history	7 submissions · 6 cleared · 2015-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k153255/> 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 24, 2026