

K162930 Aero Chrome* Select Breathable Performance Surgical Gowns

Apr 21, 2017
184 days to decision

K162930 · Product code: **FYA** · General Hospital
Source: <https://www.510kdatabase.net/k162930/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Oct 19, 2016
Decision date	Apr 21, 2017
Days to decision	184 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k162930/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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