

K192362 Aero Blue Performance Surgical GownsDec 13, 2019
105 days to decisionK192362 · Product code: **FYA** · General Hospital
Source: <https://www.510kdatabase.net/k192362/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Gown, Surgical (FYA)
Date received	Aug 30, 2019
Decision date	Dec 13, 2019
Days to decision	105 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	O&M Halyard, Inc.
Location	Alpharetta, GA, US
Contact	Kimberly Lewis
510(k) history	24 submissions · 24 cleared · 2019-2026

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