

K210688 AERO CHROME* Select Breathable Performance Surgical Gown, AERO CHROME* A-Line Breathable Performance Surgical GownJul 21, 2021
135 days to decisionK210688 · Product code: FYA · General Hospital
Source: <https://www.510kdatabase.net/k210688/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Gown, Surgical (FYA)
Date received	Mar 8, 2021
Decision date	Jul 21, 2021
Days to decision	135 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	23 submissions · 23 cleared · 2019-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k210688/> Data sourced from FDA 510(k) public records (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. - Generated May 14, 2026