

K200522 AERO CHROME* Breathable Performance Surgical Gowns

Mar 16, 2020
14 days to decision

K200522 · Product code: **FYA** · General Hospital
Source: <https://www.510kdatabase.net/k200522/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Gown, Surgical (FYA)
Date received	Mar 2, 2020
Decision date	Mar 16, 2020
Days to decision	14 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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k200522/> 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 June 28, 2026