

K183132 Halyard Pink Underguard Nitrile Powder-Free Exam Glove Tested for Use with Chemotherapy Drugs

Feb 5, 2019
84 days to decision

K183132 · Product code: **LZC** · General Hospital
Source: <https://www.510kdatabase.net/k183132/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Medical Glove, Specialty (LZC)
Date received	Nov 13, 2018
Decision date	Feb 5, 2019
Days to decision	84 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	Angela L. Bunn
510(k) history	24 submissions · 24 cleared · 2019-2026

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k183132/> 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