

K200843 Halyard Pink Underguard Zero, Sterile Powder-Free Exam Gloves Tested with Chemotherapy DrugsSep 22, 2020
175 days to decisionK200843 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k200843/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Mar 31, 2020
Decision date	Sep 22, 2020
Days to decision	175 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	Steven Dowdley
510(k) history	24 submissions · 24 cleared · 2019-2026

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