

K192241 Halyard Purple Xtra and Purple Sterile, Low Dermatitis Potential, Powder-Free Exam Gloves Tested for Use with Chemotherapy Drugs and Fentanyl Citrate

Mar 13, 2020
207 days to decision

K192241 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k192241/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Aug 19, 2019
Decision date	Mar 13, 2020
Days to decision	207 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	O&M Haylard, Inc.
Location	Alpharetta, GA, US
Contact	Steven Dowdley
510(k) history	1 submissions · 1 cleared · 2020-2020

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k192241/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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