

K211063 HALYARD Flexaprene Green Powder-Free Exam GloveNov 19, 2021
224 days to decisionK211063 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k211063/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Apr 9, 2021
Decision date	Nov 19, 2021
Days to decision	224 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	O&M Halyard, Inc.
Location	Alpharetta, GA, US
Contact	Steven Dowdley
510(k) history	23 submissions · 23 cleared · 2019-2026

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