

K143477 Nitrile Patient Examination gloves, Powderfree, Blue color

Apr 14, 2016
496 days to decision

K143477 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k143477/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Dec 5, 2014
Decision date	Apr 14, 2016
Days to decision	496 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Primus Gloves Pvt Limited
Location	Cochin, IN
Contact	JOSE PAUL M
510(k) history	3 submissions · 3 cleared · 2016-2017

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k143477/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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