

**K133699 POWDER FREE GREEN, BLUE AND BROWN
POLYCHLOROPRENE EXAMINATION GLOVES**Jul 18, 2014
227 days to decisionK133699 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k133699/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Dec 3, 2013
Decision date	Jul 18, 2014
Days to decision	227 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Pt. Smartglove Indonesia
Location	Tg Morawa-Deli Serdang Utara, ID
Contact	KHON PU FOO
510(k) history	12 submissions · 12 cleared · 2003-2014

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k133699/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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