

**K113393 POWDER FREE BLACK NITRILE EXAMINATION
GLOVES**Sep 11, 2012
299 days to decisionK113393 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k113393/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Nov 17, 2011
Decision date	Sep 11, 2012
Days to decision	299 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Tg Medical Sdn. Bhd.
Location	Kapar, Selangor D.E., MY
Contact	NOOR A SAIDIN
510(k) history	9 submissions · 9 cleared · 1994-2017

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