

K092160 POWDERFREE NITRILE (DARK BLUE) EXAMINATION GLOVESNov 27, 2009
134 days to decisionK092160 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k092160/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Jul 16, 2009
Decision date	Nov 27, 2009
Days to decision	134 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Comfort Rubber Gloves Ind. Sdn. Bhd.
Location	Taiping, Perak, MY
Contact	TAN KENG BENG
510(k) history	2 submissions · 2 cleared · 2009-2009

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k092160/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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