

K161085 Nitrile Patient Examination Powder Free Glove, Textured, Black

Jul 5, 2018
808 days to decision

K161085 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k161085/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Apr 18, 2016
Decision date	Jul 5, 2018
Days to decision	808 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Multisafe Sdn. Bhd.
Location	35500 Bidor, Perak Darul Ridzu, MY
Contact	THUM TECK LAM
510(k) history	8 submissions · 8 cleared · 2000-2018

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k161085/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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