

K183280 PowderFree White Blue Sterilized Nitrile Copolymer Examination Gloves Tested for use with chemotherapy drugsJul 26, 2019
245 days to decisionK183280 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k183280/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Nov 23, 2018
Decision date	Jul 26, 2019
Days to decision	245 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Smart Glove Corporation Sdn. Bhd.
Location	Klang, MY
Contact	Khon Pu Foo
510(k) history	5 submissions · 5 cleared · 2017-2022

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