

K171743 Powder Free Pink Polychloroprene Copolymer Examination Gloves, Powder Free Black Polychloroprene Copolymer Examination Gloves

Nov 17, 2017
158 days to decision

K171743 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k171743/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Jun 12, 2017
Decision date	Nov 17, 2017
Days to decision	158 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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k171743/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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