

K190725 Nitrile Examination Glove Sterile Tested for use with Chemotherapy Drugs Claim, White

Dec 17, 2019
272 days to decision

K190725 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k190725/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Mar 20, 2019
Decision date	Dec 17, 2019
Days to decision	272 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Riverstone Resources Sdn Bhd
Location	Kepong Baru, Kuala Lumpur, MY
Contact	Suresh Kumar
510(k) history	15 submissions · 15 cleared · 1999-2022

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k190725/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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