

K211374 Proclean - Nitrile Powder Free Examination GlovesOct 13, 2021
162 days to decisionK211374 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k211374/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	May 4, 2021
Decision date	Oct 13, 2021
Days to decision	162 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dr.Boo Company Limited
Location	Sriracha, TH
Contact	Darunee Varabuntoonvit
510(k) history	1 submissions · 1 cleared · 2021-2021

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211374/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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