

K182640 Powder Free Nitrile Examination Gloves (White, Cobalt Blue, Blue and Violet Blue)

Apr 12, 2019
200 days to decision

K182640 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k182640/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Sep 24, 2018
Decision date	Apr 12, 2019
Days to decision	200 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Shandong Hengya Packaging Printing Co.,Ltd
Location	Weifang City, CN
Contact	Sunny Hu
510(k) history	1 submissions · 1 cleared · 2019-2019

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k182640/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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