

K182554 Powder Free Nitrile Examination Gloves, Blue, Tested for Use with Chemotherapy Drugs

Mar 22, 2019
186 days to decision

K182554 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k182554/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Sep 17, 2018
Decision date	Mar 22, 2019
Days to decision	186 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	He Chuang Plastic & Rubber Co., Ltd.
Location	Zibo, CN
Contact	Coco Wang
510(k) history	1 submissions · 1 cleared · 2019-2019

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k182554/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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