FDA 510(k) Premarket Notification

K211252 Nitrile Glove

CLEARED

Jun 25, 2021
60 days to decision

K211252 · Product code: **LZA** · General Hospital
Source: https://www.510kdatabase.net/k211252/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Apr 26, 2021
Decision date	Jun 25, 2021
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Jiangsu Dihong Industry and Trade Co., Ltd.**
Location	Shuyang, CN
Contact	Sue Chen
510(k) history	2 submissions · 2 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	**Shanghai Truthful Information Technology Co., Ltd.**
Contact	Boyle Wang

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k211252/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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