

K242812 NITRILE EXAMINATION GLOVES (Tested For Use With Chemotherapy Drugs)

Oct 12, 2024
24 days to decisionK242812 · Product code: LZA · General Hospital
Source: <https://www.510kdatabase.net/k242812/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Sep 18, 2024
Decision date	Oct 12, 2024
Days to decision	24 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Nb Medical Company Limited
Location	Thai Binh Province, VN
Contact	Thi Vinh Vu
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	Wenzhou Thiwe Business Consulting Co., Ltd.
Contact	Wendy Huang

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k242812/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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