

K212899 Disposable Vinyl/Nitrile Blend Medical Examination Gloves

Dec 11, 2021
89 days to decision

K212899 · Product code: LYZ · General Hospital
Source: <https://www.510kdatabase.net/k212899/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Vinyl Patient Examination Glove (LYZ)
Date received	Sep 13, 2021
Decision date	Dec 11, 2021
Days to decision	89 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Bytech Dongtai Co., Ltd.
Location	Beijing, CN
Contact	Wang Cheng
510(k) history	2 submissions · 2 cleared · 2013-2021

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](https://accessdata.fda.gov)

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Device record: <https://www.510kdatabase.net/k212899/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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