

K211667 Disposable Medical Synthetic Nitrile Examination Gloves (Non-Sterile)Sep 23, 2021
114 days to decisionK211667 · Product code: LAZ · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k211667/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	N-acetylprocainamide Control Materials (LAZ)
Date received	Jun 1, 2021
Decision date	Sep 23, 2021
Days to decision	114 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Changzhou Universal Medical Equipment Co., Ltd.
Location	Xinbei District, CN
Contact	Jerry Gao
510(k) history	3 submissions · 3 cleared · 2021-2022

REGULATORY CONSULTANT

Consulting firm	Cnmed Consultant
Contact	Johnson Liu

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/k211667/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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