

K220491 Disposable Medical Nitrile Examination Gloves -Tested for Use with Chemotherapy DrugsMay 14, 2022
81 days to decisionK220491 · Product code: **LZC** · General Hospital
Source: <https://www.510kdatabase.net/k220491/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Medical Glove, Specialty (LZC)
Date received	Feb 22, 2022
Decision date	May 14, 2022
Days to decision	81 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Hainan Asther Medical Equipment Co., Ltd.
Location	Chengmai, CN
Contact	Viki Ye
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Cnmed Consulting
Contact	Johnson Liu

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k220491/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 27, 2026