

K214017 Examination gloves-Type A(Latex gloves)Jul 14, 2022
204 days to decisionK214017 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k214017/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Dec 22, 2021
Decision date	Jul 14, 2022
Days to decision	204 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Jiangxi Kemei Medical Apparatus & Instruments Group Co., Ltd.
Location	Nanchang, CN
Contact	Jenny Huang
510(k) history	3 submissions · 3 cleared · 2021-2022

REGULATORY CONSULTANT

Consulting firm	Shanghai Mind-Link Business Consulting Co., Ltd.
Contact	Alice Huang

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/k214017/> 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 26, 2026