

K211209 Hycare Med+ Nitrile Examination GlovesDec 17, 2021
238 days to decisionK211209 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k211209/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Apr 23, 2021
Decision date	Dec 17, 2021
Days to decision	238 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Hycare Touch Latex Examination Gloves

APPLICANT

Company	Hycare International Co., Ltd.
Location	Khuanlang Hatyai, TH
Contact	Tippawan Phongpheaw
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Accurate Consulting, Inc.
Contact	Sebastian Feye

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/k211209/> 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