

K221648 Iconic Latex GloveAug 25, 2022
79 days to decisionK221648 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k221648/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Jun 7, 2022
Decision date	Aug 25, 2022
Days to decision	79 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Iconic Medicare Sdn Bhd
Location	Kuala Lumpur, MY
Contact	Tan Cho Chia
510(k) history	3 submissions · 3 cleared · 2021-2023

REGULATORY CONSULTANT

Consulting firm	Integrated Assessment Services Pvt, Ltd.
Contact	A.C. Thirumaran

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/k221648/> 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