FDA 510(k) Premarket Notification

K221185 TC Gloves

CLEARED

Jun 22, 2022
58 days to decision

K221185 · Product code: **LYY** · General Hospital
Source: https://www.510kdatabase.net/k221185/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Apr 25, 2022
Decision date	Jun 22, 2022
Days to decision	58 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Thanh Cong Pharmaceutical and Trading Company Limited**
Location	Bac Ninh City, VN
Contact	Nguyen Thi Tu Anh
510(k) history	2 submissions · 2 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	**Liberty Management Group Limited**
Contact	Manoj Zacharias

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k221185/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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