

K212438 ComfortproDec 7, 2021
125 days to decisionK212438 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k212438/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Latex Patient Examination Glove (LYY)
Date received	Aug 4, 2021
Decision date	Dec 7, 2021
Days to decision	125 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Thai Rubber Industry Company Limited
Location	Pluakdaeng, TH
Contact	Chawalit Tiyadechachai
510(k) history	2 submissions · 2 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Liberty Management Group , Ltd.
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.netDevice record: <https://www.510kdatabase.net/k212438/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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