

K213073 Goody Gloves, Wincare, TBG GlovesDec 29, 2021
97 days to decisionK213073 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k213073/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Latex Patient Examination Glove (LYY)
Date received	Sep 23, 2021
Decision date	Dec 29, 2021
Days to decision	97 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Thai Rubber Gloves Co., Ltd.
Location	Nongyai, TH
Contact	Chalongkwan Wongsasuthikul
510(k) history	2 submissions · 2 cleared · 2021-2022

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

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