

K213075 Goody Gloves, Wincare, TBG GlovesJan 20, 2022
119 days to decisionK213075 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k213075/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Sep 23, 2021
Decision date	Jan 20, 2022
Days to decision	119 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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