FDA 510(k) Premarket Notification

CLEARED

K222693 Single-use medical latex examination gloves (LG100)

Sep 24, 2022
18 days to decision

K222693 · Product code: **LYY** · General Hospital
Source: https://www.510kdatabase.net/k222693/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Sep 6, 2022
Decision date	Sep 24, 2022
Days to decision	18 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Fitone Latex Products Co., Ltd. Guangdong**
Location	Zhanjiang, CN
Contact	Christine Ou
510(k) history	4 submissions · 4 cleared · 2021-2023

REGULATORY CONSULTANT

Consulting firm	**Landlink Healthcare Technology (Shanghai) Co., Ltd.**
Contact	Stuart Situ

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