FDA 510(k) Premarket Notification

K230777 Patient Examination Gloves

CLEARED

Oct 6, 2023
199 days to decision

K230777 · Product code: **LZA** · General Hospital
Source: https://www.510kdatabase.net/k230777/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Mar 21, 2023
Decision date	Oct 6, 2023
Days to decision	199 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**3A Glove Sdn. Bhd.**
Location	Senai, MY
Contact	Kumar Durarajen
510(k) history	2 submissions · 2 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**Shanghai Truthful Information Technology Co., Ltd.**
Contact	Boyle Wang

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