

**K162626 THERMOPLASTIC POLYETHYLENE EXAMINATION
(TPE) GLOVE**Mar 31, 2017
192 days to decisionK162626 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k162626/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Sep 20, 2016
Decision date	Mar 31, 2017
Days to decision	192 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Top Quality Glove Sdn. Bhd
Location	Klang, MY
Contact	HUE KON FAH
510(k) history	1 submissions · 1 cleared · 2017-2017

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k162626/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 1, 2026