

**K210587 Violet Nitrile Powder Free Patient Examination Glove,
Non Sterile**Jun 28, 2021
122 days to decisionK210587 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k210587/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Feb 26, 2021
Decision date	Jun 28, 2021
Days to decision	122 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Onetexx Sdn Bhd
Location	Kamunting, MY
Contact	Freddy Low
510(k) history	7 submissions · 7 cleared · 2021-2022

REGULATORY CONSULTANT

Consulting firm	Emergo Global Representation
Contact	Michael Van der Woude

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k210587/>; 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 May 26, 2026