

**K211310 AMADEX - Nitrile Powder Free Examination Gloves
Non-Sterile (Blue, Black, Orange)**Jun 16, 2021
47 days to decisionK211310 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k211310/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Apr 30, 2021
Decision date	Jun 16, 2021
Days to decision	47 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Megine Industries Sdn Bhd
Location	Kuala Lumpur, MY
Contact	Benjamin Ng Soong Jing
510(k) history	2 submissions · 2 cleared · 2021-2022

REGULATORY CONSULTANT

Consulting firm	Regulatory Technology Services, LLC
Contact	Prithul Bom

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

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