

K211808 Medicare Powder-Free Blue Nitrile Patient Examination GlovesMar 4, 2022
266 days to decisionK211808 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k211808/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Jun 11, 2021
Decision date	Mar 4, 2022
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dongguan Grinvald Technology Co., Ltd.
Location	Dongguan, CN
Contact	Anna Roxana Grinvald
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Mdi Consultants, Inc.
Contact	Aristotle Nafpliotis

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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