

**K220693 Zoupure Nitrile Powder Free Examination glove**Jun 7, 2022  
90 days to decisionK220693 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k220693/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Mar 9, 2022
Decision date	Jun 7, 2022
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Thai Rayong Product Glove Zoupure Co., Ltd.</b>
Location	Bankhai, TH
Contact	Rattiya Pitutacha
510(k) history	1 submissions · 1 cleared · 2022-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>Regulatory Insight, Inc.</b>
Contact	Kevin Walls

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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