

**K211182 H2H Powder Free Examination Blue Glove**Aug 1, 2021  
103 days to decisionK211182 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k211182/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Apr 20, 2021
Decision date	Aug 1, 2021
Days to decision	103 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Ntl Innovation Co., Ltd.</b>
Location	Hatyai District, TH
Contact	Puttharaksa Sornkong
510(k) history	1 submissions · 1 cleared · 2021-2021

**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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