

**K190454 Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl, Citrate (Blue), Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl, Citrate (Blue) - Extended Cuff**

Sep 26, 2019  
213 days to decision

K190454 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k190454/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Feb 25, 2019
Decision date	Sep 26, 2019
Days to decision	213 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Hartalega NGC Sdn. Bhd.</b>
Location	Bandar Sri Damansara, MY
Contact	Kuan Kam Hon
510(k) history	28 submissions · 28 cleared · 2014-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Hartalega Sdn Bhd</b>
Contact	Nurul Aisyah Kong

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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