

**K200019 Nitrile Powder Free Examination Gloved Tested for Use with Chemotherapy Drugs and Fentanyl, Citrate (Blue), Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl, Citrate (Black)**Apr 6, 2020  
94 days to decisionK200019 · Product code: **LZA** · General HospitalSource: <https://www.510kdatabase.net/k200019/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Jan 3, 2020
Decision date	Apr 6, 2020
Days to decision	94 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 Mun Leong
510(k) history	28 submissions · 28 cleared · 2014-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k200019/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 28, 2026