

**K192444 mCare® Powder Free Nitrile Black Examination Glove**Dec 31, 2019  
116 days to decisionK192444 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k192444/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Sep 6, 2019
Decision date	Dec 31, 2019
Days to decision	116 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Mercator Medical (Thailand), Ltd.</b>
Location	Littleton, CO, US
Contact	Praneet Inthajak
510(k) history	7 submissions · 7 cleared · 2015-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k192444/> 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 May 25, 2026