

K220375 Intercept Free, Nitrile Two Toned White/Green, Textured Fingertips, Powder-Free, Non-sterile, Ambidextrous, Beaded Cuff, Medical Examination Gloves, Tested for Use with Opioids Fentanyl citrate, Heroin, and both Opioids in simulated Gastric Acid (Vomit)

Apr 13, 2022
63 days to decision

K220375 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k220375/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Feb 9, 2022
Decision date	Apr 13, 2022
Days to decision	63 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Summit Glove, Inc.
Location	Minerva, OH, US
Contact	James Hull
510(k) history	5 submissions · 5 cleared · 2010-2022

REGULATORY CONSULTANT

Consulting firm	Truscott Medsci Associates, LLC
Contact	Wava Truscott

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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Device record: <https://www.510kdatabase.net/k220375/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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