

K220371 Nitrile Two Toned Blue/Green, Powder-Free, Non-sterile, Ambidextrous, Beaded Cuff, Medical Grade Exam Gloves, Tested for Use with the Opioids Fentanyl citrate, Heroin, and both Opioids in simulated Gastric Acid (Vomit)Nov 2, 2022
266 days to decisionK220371 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k220371/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Feb 9, 2022
Decision date	Nov 2, 2022
Days to decision	266 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

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