

**K013254 POLYCOAT POWDERED LATEX EXAMINATION
GLOVE WITH ALOE VERA & PROTEIN CONTENT LABELING
CLAIM (200 MICROGRAMS OR LESS)**

Feb 4, 2002
129 days to decision

K013254 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k013254/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Sep 28, 2001
Decision date	Feb 4, 2002
Days to decision	129 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Top Quality Mfg., Inc.
Location	New Port Riche, FL, US
Contact	ART WARD
510(k) history	4 submissions · 4 cleared · 2000-2002

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k013254/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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