

**K212633 Disposable Isolation Gown -Level 3, Large, Blue,
Disposable Isolation Gown - Level 3, X-Large, Blue**Nov 24, 2021
97 days to decisionK212633 · Product code: FYC · General Hospital
Source: <https://www.510kdatabase.net/k212633/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Isolation, Surgical (FYC)
Date received	Aug 19, 2021
Decision date	Nov 24, 2021
Days to decision	97 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	String King Lacrosse, LLC
Location	Gardena, CA, US
Contact	Thomas Frasca
510(k) history	2 submissions · 2 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Medical Device Academy, Inc.
Contact	Sharon Morrow

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212633/> Data sourced from FDA 510(k) public records (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. - Generated May 24, 2026