

K252575 Tuff Cuff™ Disposable Surgical Gowns AAMI L4 Sterile-Large (ML-L4-STL-DC-L)Jun 4, 2026
294 days to decisionK252575 · Product code: FYA · General Hospital
Source: <https://www.510kdatabase.net/k252575/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Aug 14, 2025
Decision date	Jun 4, 2026
Days to decision	294 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	New York Embroidery Studio (NYES)
Location	New York, NY, US
Contact	Michelle Feinburg
510(k) history	1 submissions · 1 cleared · 2026-2026

REGULATORY CONSULTANT

Consulting firm	Medical Devices Academy, Inc.
Contact	Rob Packard

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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