

K261949 NYES Tuff Cuff L3 Disposable Gowns

Jul 10, 2026
29 days to decision

K261949 · Product code: FYA · General Hospital
Source: <https://www.510kdatabase.net/k261949/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Gown, Surgical (FYA)
Date received	Jun 11, 2026
Decision date	Jul 10, 2026
Days to decision	29 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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