

**K000901 KLINIDRAPE SURGICAL GOWNS, NON-REINFORCED,
BASIC PROTECTIONS AND STANDARD PROTECTION**Jul 5, 2000
106 days to decisionK000901 · Product code: FYA · General Hospital
Source: <https://www.510kdatabase.net/k000901/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Mar 21, 2000
Decision date	Jul 5, 2000
Days to decision	106 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Molnlycke Health Care, Inc.
Location	Eddystone, PA, US
Contact	MIGUEL A NEGRON
510(k) history	10 submissions · 9 cleared · 1998-2006

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k000901/> 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 June 29, 2026