

K984422 STERILE BACK SURGICAL GOWN WITH HAND TOWELApr 2, 1999
113 days to decisionK984422 · Product code: FYA · General Hospital
Source: <https://www.510kdatabase.net/k984422/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Dec 10, 1998
Decision date	Apr 2, 1999
Days to decision	113 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Medical Sterilization, Inc.
Location	NY, US
Contact	DAVID MORGANSTERN
510(k) history	6 submissions · 6 cleared · 1984-1999

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k984422/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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