

K052833 GORE-TEX NON-STERILE SURGICAL GOWNSFeb 15, 2006
132 days to decisionK052833 · Product code: **KKX** · General Hospital
Source: <https://www.510kdatabase.net/k052833/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Drape, Surgical (KKX)
Date received	Oct 6, 2005
Decision date	Feb 15, 2006
Days to decision	132 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Medline Industries, Inc.
Location	Mchenry, IL, US
Contact	JENNIFER MASON
510(k) history	238 submissions · 234 cleared · 1977-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k052833/> 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 26, 2026