

K951214 STERILE EQUIPMENT COVERMay 16, 1995
60 days to decisionK951214 · Product code: **KKX** · General Hospital
Source: <https://www.510kdatabase.net/k951214/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drape, Surgical (KKX)
Date received	Mar 17, 1995
Decision date	May 16, 1995
Days to decision	60 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Gulfstream Medical
Location	Winthrop, MA, US
Contact	ALEX WITHERS
510(k) history	2 submissions · 2 cleared · 1995-1995

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k951214/> 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 July 6, 2026