

K904694 CUSTOMED ANGIODRAPE PACK FEMORALJan 2, 1991
78 days to decisionK904694 · Product code: **KKX** · General Hospital
Source: <https://www.510kdatabase.net/k904694/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - K
Submission type	Traditional
Device classification	Drape, Surgical (KKX)
Date received	Oct 16, 1990
Decision date	Jan 2, 1991
Days to decision	78 days
Third-party review	No

APPLICANT

Company	Customed, Inc.
Location	Carolina Puerto Rico, US
Contact	JOSE M NEGRON
510(k) history	36 submissions · 26 cleared · 1990-1998

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k904694/>; 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 May 26, 2026