

K973981 SAFEPASS STERILIZATION POUCH

Jan 29, 1998
 101 days to decision

K973981 · Product code: **KCT** · General Hospital
 Source: <https://www.510kdatabase.net/k973981/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sterilization Wrap Containers, Trays, Cassettes & Other Accessories (KCT)
Date received	Oct 20, 1997
Decision date	Jan 29, 1998
Days to decision	101 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Adroit Medical Systems, Inc.
Location	Morganton, NC, US
Contact	RICHARD L STUDER
510(k) history	6 submissions · 6 cleared · 1992-2008

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k973981/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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