

K944252 BIOPSY DEVICE ACCESSORYDec 5, 1994
97 days to decisionK944252 · Product code: **FCK** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k944252/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Biopsy, Suction (FCK)
Date received	Aug 30, 1994
Decision date	Dec 5, 1994
Days to decision	97 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biopsys Medical, Inc.
Location	San Juan Capistrano, CA, US
Contact	MARK A COLE
510(k) history	15 submissions · 15 cleared · 1994-1997

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k944252/> 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 20, 2026