

K933948 ACUFEX ENDOBUTTON SYSTEMJul 21, 1994
343 days to decisionK933948 · Product code: **MAI** · Orthopedic
Source: <https://www.510kdatabase.net/k933948/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Biodegradable, Soft Tissue (MAI)
Date received	Aug 12, 1993
Decision date	Jul 21, 1994
Days to decision	343 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Acufex Microsurgical, Inc.
Location	Mchenry, IL, US
Contact	FREDERICK TOBIA
510(k) history	78 submissions · 75 cleared · 1980-1996

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k933948/> 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 14, 2026