

K946346 ACUFEX TAG(R) BIOABSORBABLE ANCHORSApr 26, 1995
117 days to decisionK946346 · Product code: **JDR** · Orthopedic
Source: <https://www.510kdatabase.net/k946346/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Staple, Fixation, Bone (JDR)
Date received	Dec 30, 1994
Decision date	Apr 26, 1995
Days to decision	117 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/k946346/> 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