

K931519 ACUFEX SURETACJun 16, 1994
447 days to decisionK931519 · Product code: **JDR** · Orthopedic
Source: <https://www.510kdatabase.net/k931519/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Staple, Fixation, Bone (JDR) |
| Date received | Mar 26, 1993 |
| Decision date | Jun 16, 1994 |
| Days to decision | 447 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

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

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