

K965228 FASTERNER, FIXATION, BIODEGRADABLE SOFT TISSUENov 10, 1997
314 days to decisionK965228 · Product code: **MAI** · Orthopedic
Source: <https://www.510kdatabase.net/k965228/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Biodegradable, Soft Tissue (MAI)
Date received	Dec 31, 1996
Decision date	Nov 10, 1997
Days to decision	314 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	United States Surgical, A Division of Tyco Healthc
Location	Mchenry, IL, US
Contact	MELISSA MAZZONI
510(k) history	218 submissions · 200 cleared · 1977-2007

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k965228/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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