

K963396 BIOSPHERE SUTURE ANCHORMay 6, 1997
251 days to decisionK963396 · Product code: **MAI** · Orthopedic
Source: <https://www.510kdatabase.net/k963396/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Biodegradable, Soft Tissue (MAI)
Date received	Aug 28, 1996
Decision date	May 6, 1997
Days to decision	251 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Instrument Makar, Inc.
Location	Mchenry, IL, US
Contact	ANDREW P ABOOD
510(k) history	28 submissions · 27 cleared · 1979-2000

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