

K981340 INNOVASIVE DEVICES MENISCAL DART REPAIR SYSTEMJun 22, 1998
70 days to decisionK981340 · Product code: **MAI** · Orthopedic
Source: <https://www.510kdatabase.net/k981340/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Biodegradable, Soft Tissue (MAI)
Date received	Apr 13, 1998
Decision date	Jun 22, 1998
Days to decision	70 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Innovasive Devices, Inc.
Location	Hopkinton, MA, US
Contact	ERIC BANNON
510(k) history	34 submissions · 31 cleared · 1993-2000

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k981340/>. 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