

**K971922 INNOVASIVE 2.8MM AND 3.5MM ROC EZ SUTURE  
BONE FASTENER**Aug 7, 1997  
76 days to decisionK971922 · Product code: **MBI** · Orthopedic  
Source: <https://www.510kdatabase.net/k971922/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	May 23, 1997
Decision date	Aug 7, 1997
Days to decision	76 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Innovasive Devices, Inc.</b>
Location	Hopkinton, MA, US
Contact	STEPHEN M PAGE
510(k) history	34 submissions · 31 cleared · 1993-2000

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k971922/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 14, 2026