

**K951565 INNOVASIVE DEVICES ROTATOR CUFF FASTENER**Sep 8, 1995  
157 days to decisionK951565 · Product code: **MBI** · Orthopedic  
Source: <https://www.510kdatabase.net/k951565/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Apr 4, 1995
Decision date	Sep 8, 1995
Days to decision	157 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Innovasive Devices, Inc.</b>
Location	Hopkinton, MA, US
Contact	ERIV BANNON
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/k951565/> 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