

**K963402 INNOVASIVE 2.8MM ROC SUTURE BONE FASTENER  
AND 3.5MM ROC SUTURE BONE FASTENER**

Nov 4, 1996  
67 days to decision

K963402 · Product code: **MBI** · Orthopedic  
Source: <https://www.510kdatabase.net/k963402/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Aug 29, 1996
Decision date	Nov 4, 1996
Days to decision	67 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Innovasive Devices, Inc.</b>
Location	Hopkinton, MA, US
Contact	ERIC 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/k963402/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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