

**K972438 INNOVASIVE 2.3MM ROC XS SUTURE BONE FASTENER**

Sep 26, 1997  
88 days to decision

K972438 · Product code: **MBI** · Orthopedic  
Source: <https://www.510kdatabase.net/k972438/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Jun 30, 1997
Decision date	Sep 26, 1997
Days to decision	88 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 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/k972438/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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