

**K954338 INNOVASIVE 1.9MM ROC SUTURE BONE FASTENER**Mar 21, 1996  
185 days to decisionK954338 · Product code: **MBI** · Orthopedic  
Source: <https://www.510kdatabase.net/k954338/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent - SN
Submission type	Traditional
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Sep 18, 1995
Decision date	Mar 21, 1996
Days to decision	185 days
Third-party review	No

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k954338/>; 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