

**K944831 INNOVASIVE 1.9MM, 2.8MM, 3.5MM, 4.5MM ROC
SUTURE BONE FASTENER**Feb 1, 1995
125 days to decisionK944831 · Product code: **MBI** · Orthopedic
Source: <https://www.510kdatabase.net/k944831/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - SN
Submission type	Traditional
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Sep 29, 1994
Decision date	Feb 1, 1995
Days to decision	125 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k944831/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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