

K981193 INNOVASIVE 3.5MM METAL ROC XS SUTURE BONE FASTENERJun 16, 1998
75 days to decisionK981193 · Product code: **MBI** · Orthopedic
Source: <https://www.510kdatabase.net/k981193/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Fastener, Fixation, Nondegradable, Soft Tissue (MBI) |
| Date received | Apr 2, 1998 |
| Decision date | Jun 16, 1998 |
| Days to decision | 75 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k981193/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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