

K063577 FEMORAL INTRAFIX SCREW AND SHEATHJan 25, 2007
56 days to decisionK063577 · Product code: **MBI** · Orthopedic
Source: <https://www.510kdatabase.net/k063577/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Fastener, Fixation, Nondegradable, Soft Tissue (MBI) |
| Date received | Nov 30, 2006 |
| Decision date | Jan 25, 2007 |
| Days to decision | 56 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Johnson & Johnson Company |
| Location | Raynham, MA, US |
| Contact | Ruth Forstadt |
| 510(k) history | 2 submissions · 2 cleared · 2006-2007 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k063577/> Data sourced from FDA 510(k) public records (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. - Generated May 14, 2026