

K083609 KFX PEEK BONE ANCHOR WITH PRE-ATTACHED SUTURES AND INSERTER HANDLEMar 6, 2009
88 days to decisionK083609 · Product code: **MBI** · Orthopedic
Source: <https://www.510kdatabase.net/k083609/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Fastener, Fixation, Nondegradable, Soft Tissue (MBI) |
| Date received | Dec 8, 2008 |
| Decision date | Mar 6, 2009 |
| Days to decision | 88 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Kfx Medical |
| Location | Carlsbad, CA, US |
| Contact | GAYLE HIROTA |
| 510(k) history | 7 submissions · 7 cleared · 2006-2012 |

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