

K982571 KSEA FLIPPTACKSep 22, 1998
60 days to decisionK982571 · Product code: **MBI** · Orthopedic
Source: <https://www.510kdatabase.net/k982571/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Fastener, Fixation, Nondegradable, Soft Tissue (MBI) |
| Date received | Jul 24, 1998 |
| Decision date | Sep 22, 1998 |
| Days to decision | 60 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | KARL STORZ Endoscopy-America, Inc. |
| Location | Mchenry, IL, US |
| Contact | KEVIN KENNAN |
| 510(k) history | 361 submissions · 361 cleared · 1980-2024 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k982571/> 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