

K173824 Humeral Short Stem SystemOct 23, 2018
309 days to decisionK173824 · Product code: **MBF** · Orthopedic
Source: <https://www.510kdatabase.net/k173824/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Prosthesis, Shoulder, Semi-constrained, Metal/polymer, Uncemented (MBF) |
| Date received | Dec 18, 2017 |
| Decision date | Oct 23, 2018 |
| Days to decision | 309 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Shoulder Innovations, Inc. |
| Location | Holland, MI, US |
| Contact | Don Running |
| 510(k) history | 8 submissions · 8 cleared · 2018-2026 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k173824/> 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 26, 2026