

K180729 FaSet Fixation SystemJun 28, 2018
100 days to decisionK180729 · Product code: **MRW** · Orthopedic
Source: <https://www.510kdatabase.net/k180729/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Facet Screw Spinal Device (MRW) |
| Date received | Mar 20, 2018 |
| Decision date | Jun 28, 2018 |
| Days to decision | 100 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Huvexel Co. , Ltd. |
| Location | Seongnam-Si, KR |
| Contact | Sung Hee-Lee |
| 510(k) history | 8 submissions · 8 cleared · 2017-2022 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k180729/> 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 27, 2026