

K090224 FORTEX PEDICLE SCREW SYSTEMJul 30, 2009
181 days to decisionK090224 · Product code: **MNH** · Orthopedic
Source: <https://www.510kdatabase.net/k090224/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Orthosis, Spondylolisthesis Spinal Fixation (MNH) |
| Date received | Jan 30, 2009 |
| Decision date | Jul 30, 2009 |
| Days to decision | 181 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | X-Spine Systems, Inc. |
| Location | Centerville, OH, US |
| Contact | DAVID KIRSCHMAN |
| 510(k) history | 34 submissions · 34 cleared · 2005-2018 |

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