

K072434 SYNTHES OC FUSION AND SYNAPSE SYSTEMSJan 10, 2008
134 days to decisionK072434 · Product code: **MNI** · Orthopedic
Source: <https://www.510kdatabase.net/k072434/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Orthosis, Spinal Pedicle Fixation (MNI) |
| Date received | Aug 29, 2007 |
| Decision date | Jan 10, 2008 |
| Days to decision | 134 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Synthes Spine Co.Lp |
| Location | West Chester, PA, US |
| Contact | SUSAN LEWANDOWSKI |
| 510(k) history | 18 submissions · 18 cleared · 2005-2012 |

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