

K013431 PASS SPINAL SYSTEMNov 15, 2001
30 days to decisionK013431 · Product code: **MNI** · Orthopedic
Source: <https://www.510kdatabase.net/k013431/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Orthosis, Spinal Pedicle Fixation (MNI) |
| Date received | Oct 16, 2001 |
| Decision date | Nov 15, 2001 |
| Days to decision | 30 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Encore Orthopedics, Inc. |
| Location | Red Rock, TX, US |
| Contact | JOANNA DROEGE |
| 510(k) history | 85 submissions · 74 cleared · 1993-2004 |

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