

K980485 ISOLA SPINAL SYSTEMOct 21, 1998
254 days to decisionK980485 · Product code: **MNI** · Orthopedic
Source: <https://www.510kdatabase.net/k980485/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Orthosis, Spinal Pedicle Fixation (MNI) |
| Date received | Feb 9, 1998 |
| Decision date | Oct 21, 1998 |
| Days to decision | 254 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Acromed Corp. |
| Location | Cleveland, OH, US |
| Contact | WILLIAM CHRISTIANSON |
| 510(k) history | 41 submissions · 22 cleared · 1984-1998 |

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