

K073643 TRANS1 AXIALIF 2-LEVEL OR II SYSTEMApr 28, 2008
124 days to decisionK073643 · Product code: **KWQ** · Orthopedic
Source: <https://www.510kdatabase.net/k073643/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Appliance, Fixation, Spinal Intervertebral Body (KWQ) |
| Date received | Dec 26, 2007 |
| Decision date | Apr 28, 2008 |
| Days to decision | 124 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Trans1 Incorporated |
| Location | Wilmington, NC, US |
| Contact | ROBERT SHERIDAN |
| 510(k) history | 9 submissions · 9 cleared · 2005-2012 |

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