

K914306 TSRH(TM) LATERAL OFFSET PLATEJun 19, 1992
268 days to decisionK914306 · Product code: **KWP** · Orthopedic
Source: <https://www.510kdatabase.net/k914306/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Appliance, Fixation, Spinal Interlaminar (KWP) |
| Date received | Sep 25, 1991 |
| Decision date | Jun 19, 1992 |
| Days to decision | 268 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Sofamor Danek Mfg., Inc. |
| Location | Memphis, TN, US |
| Contact | RICHARD W TREHARNE |
| 510(k) history | 23 submissions · 12 cleared · 1992-1995 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k914306/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 21, 2026