

K961633 CD HORIZON SPINAL SYSTEMDec 5, 1996
220 days to decisionK961633 · Product code: **KWP** · Orthopedic
Source: <https://www.510kdatabase.net/k961633/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------------------|
| Decision | Substantially Equivalent - SN |
| Submission type | Traditional |
| Device classification | Appliance, Fixation, Spinal Interlaminar (KWP) |
| Date received | Apr 29, 1996 |
| Decision date | Dec 5, 1996 |
| Days to decision | 220 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|-----------------------------------------|
| Company | Sofamor Danek USA, Inc. |
| Location | Memphis, TN, US |
| Contact | RICHARD W TREHARNE, PH.D. |
| 510(k) history | 41 submissions · 26 cleared · 1995-2000 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k961633/>; 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