

**K964623 TITANIUM CD HORIZON ANTERIOR SPINAL SYSTEM**Feb 6, 1997  
80 days to decisionK964623 · Product code: **KWQ** · Orthopedic  
Source: <https://www.510kdatabase.net/k964623/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent - SN                         |
| Submission type       | Traditional   |
| Device classification | Appliance, Fixation, Spinal Intervertebral Body (KWQ) |
| Date received         | Nov 18, 1996  |
| Decision date         | Feb 6, 1997   |
| Days to decision      | 80 days   |
| Third-party review    | No  |

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k964623/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 21, 2026