

K904243 TSRH VARIABLE ANGLE SACRAL SCREWJan 22, 1992
495 days to decisionK904243 · Product code: **KWP** · Orthopedic
Source: <https://www.510kdatabase.net/k904243/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - SN
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Interlaminar (KWP)
Date received	Sep 14, 1990
Decision date	Jan 22, 1992
Days to decision	495 days
Third-party review	No

APPLICANT

Company	Danek Medical, Inc.
Location	Mchenry, IL, US
Contact	FRANK LEWIS
510(k) history	56 submissions · 47 cleared · 1981-2000

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k904243/>; 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