

K043522 ISSYS PEDICLE SCREW SYSTEMJan 14, 2005
25 days to decisionK043522 · Product code: **KWP** · Orthopedic
Source: <https://www.510kdatabase.net/k043522/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Interlaminar (KWP)
Date received	Dec 20, 2004
Decision date	Jan 14, 2005
Days to decision	25 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Custom Spine, Inc.
Location	Conway, NH, US
Contact	DEBBIE IAMPIETRO
510(k) history	12 submissions · 12 cleared · 2005-2015

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k043522/> 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 17, 2026