

**K980928 SYNTHES SPINE UNIVERSAL SPINAL HOOK, ROD,
PEDICLE/SACRAL SCREW FIXATION SYSTEM**May 11, 1998
61 days to decisionK980928 · Product code: **KWP** · Orthopedic
Source: <https://www.510kdatabase.net/k980928/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Interlaminar (KWP)
Date received	Mar 11, 1998
Decision date	May 11, 1998
Days to decision	61 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Synthes Spine
Location	Paoli, PA, US
Contact	BARRY E SANDS
510(k) history	36 submissions · 32 cleared · 1995-2012

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k980928/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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