

K133094 CERTEX OCT SPINAL IMPLANT SYSTEMDec 11, 2013
72 days to decisionK133094 · Product code: **KWP** · Orthopedic
Source: <https://www.510kdatabase.net/k133094/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Interlaminar (KWP)
Date received	Sep 30, 2013
Decision date	Dec 11, 2013
Days to decision	72 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	X-Spine Systems, Inc.
Location	Centerville, OH, US
Contact	DAVID KIRSCHMAN, M.D.
510(k) history	34 submissions · 34 cleared · 2005-2018

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