

K112595 COFLEX-FFeb 13, 2012
159 days to decisionK112595 · Product code: **KWP** · Orthopedic
Source: <https://www.510kdatabase.net/k112595/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Interlaminar (KWP)
Date received	Sep 7, 2011
Decision date	Feb 13, 2012
Days to decision	159 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Paradigm Spine, LLC
Location	Washington, DC, US
Contact	MARC VISCOGLIOSI
510(k) history	11 submissions · 4 cleared · 2008-2016

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