

K100354 PRIMAL OK INTERSPINOUS FUSION SYSTEMAug 17, 2010
186 days to decisionK100354 · Product code: **KWP** · Orthopedic
Source: <https://www.510kdatabase.net/k100354/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Interlaminar (KWP)
Date received	Feb 12, 2010
Decision date	Aug 17, 2010
Days to decision	186 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Osteomed LP
Location	Addison, TX, US
Contact	KAREN E WARDEN
510(k) history	29 submissions · 29 cleared · 2003-2015

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