

K122378 NEXTGEN ALTIUS OCT SYSTEMSep 20, 2012
45 days to decisionK122378 · Product code: **KWP** · Orthopedic
Source: <https://www.510kdatabase.net/k122378/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Appliance, Fixation, Spinal Interlaminar (KWP)
Date received	Aug 6, 2012
Decision date	Sep 20, 2012
Days to decision	45 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biomet Spine (Aka Ebi, LLC)
Location	Parsippany, NJ, US
Contact	VIVIAN KELLY
510(k) history	13 submissions · 13 cleared · 2010-2014

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