

K061765 KALIX II IMPLANTJul 18, 2006
26 days to decisionK061765 · Product code: **HWC** · Orthopedic
Source: <https://www.510kdatabase.net/k061765/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Screw, Fixation, Bone (HWC)
Date received	Jun 22, 2006
Decision date	Jul 18, 2006
Days to decision	26 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	New Deal, S.A.
Location	Potomac, MD, US
Contact	JUDITH E O'GRADY
510(k) history	28 submissions · 28 cleared · 1999-2007

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