

K053093 KALIX II IMPLANT, MODEL 141 OXX WITH XXDec 7, 2005
34 days to decisionK053093 · Product code: **HWC** · Orthopedic
Source: <https://www.510kdatabase.net/k053093/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Screw, Fixation, Bone (HWC)
Date received	Nov 3, 2005
Decision date	Dec 7, 2005
Days to decision	34 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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