

K110046 ATHENA PEDICLE SCREW SYSTEMDec 7, 2011
335 days to decisionK110046 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k110046/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Jan 6, 2011
Decision date	Dec 7, 2011
Days to decision	335 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Royal Oak Medical Devices
Location	Bloomfield Hills, MI, US
Contact	MATHEW KROLL
510(k) history	2 submissions · 2 cleared · 2011-2011

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