

K052151 SYNTHES PANGEA MONOAXIAL SYSTEMDec 7, 2005
121 days to decisionK052151 · Product code: **NKB** · Orthopedic
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Aug 8, 2005
Decision date	Dec 7, 2005
Days to decision	121 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Synthes Spine Co.Lp
Location	West Chester, PA, US
Contact	ANGELA MIKROULIS
510(k) history	18 submissions · 18 cleared · 2005-2012

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