

K110588 LEUCADIA PEDICLE SCREW SYSTEMMay 25, 2011
84 days to decisionK110588 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k110588/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Mar 2, 2011
Decision date	May 25, 2011
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Phygen, LLC
Location	Irvine, CA, US
Contact	HARTMUT LOCH
510(k) history	7 submissions · 7 cleared · 2011-2012

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