

**K110679 DEL MAR MONOAXIAL PEDICLE SCREW SYSTEM**Aug 2, 2011  
145 days to decisionK110679 · Product code: **NKB** · Orthopedic  
Source: <https://www.510kdatabase.net/k110679/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Mar 10, 2011
Decision date	Aug 2, 2011
Days to decision	145 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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