

**K063453 VERTEFIX PEDICLE SCREW SPINAL SYSTEM**Aug 30, 2007  
288 days to decisionK063453 · Product code: **MNI** · Orthopedic  
Source: <https://www.510kdatabase.net/k063453/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Spinal Pedicle Fixation (MNI)
Date received	Nov 15, 2006
Decision date	Aug 30, 2007
Days to decision	288 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Elite Surgical Supplies (Pty), Ltd.</b>
Location	Marietta, GA, US
Contact	CHARISE DE BARRIOS
510(k) history	4 submissions · 4 cleared · 2007-2020

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