

**K170543 VIPER PRIME™ Screws with Fenestrations**May 4, 2017  
69 days to decisionK170543 · Product code: **NKB** · Orthopedic  
Source: <https://www.510kdatabase.net/k170543/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Feb 24, 2017
Decision date	May 4, 2017
Days to decision	69 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medos International SARL</b>
Location	Raynham, MA, US
Contact	Karen Sylvia
510(k) history	96 submissions · 96 cleared · 2010-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k170543/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 16, 2026