

**K083567 GII SPINAL FIXATION SYSTEM, GII-TI-POLY AXIAL SCREW**

Sep 14, 2009  
285 days to decision

K083567 · Product code: **MNH** · Orthopedic  
Source: <https://www.510kdatabase.net/k083567/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthosis, Spondylolisthesis Spinal Fixation (MNH)
Date received	Dec 3, 2008
Decision date	Sep 14, 2009
Days to decision	285 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Co-Ligne AG</b>
Location	Montreal, CA
Contact	DAVID W SCHLERF
510(k) history	4 submissions · 4 cleared · 2004-2009

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k083567/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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