

**K132644 LOSPA IS PEDICLE SCREW (MONOAXIAL & POLYAXIAL), LOSPA IS ROD- STRAIGHT (STANDARD), LOSPA IS ROD- PRE BENT (STANDARD & BU**Sep 19, 2013  
24 days to decisionK132644 · Product code: **MNI** · Orthopedic  
Source: <https://www.510kdatabase.net/k132644/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthosis, Spinal Pedicle Fixation (MNI)
Date received	Aug 26, 2013
Decision date	Sep 19, 2013
Days to decision	24 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Corentec Co., Ltd.</b>
Location	West Cadwell, NJ, US
Contact	J.S. DANIEL
510(k) history	33 submissions · 33 cleared · 2010-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k132644/>; 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 17, 2026