

**K112493 PASS LP SPINAL SYSTEM**Nov 21, 2011  
84 days to decisionK112493 · Product code: **MNI** · Orthopedic  
Source: <https://www.510kdatabase.net/k112493/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthosis, Spinal Pedicle Fixation (MNI)
Date received	Aug 29, 2011
Decision date	Nov 21, 2011
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Medicrea International</b>
Location	Round Rock, TX, US
Contact	J.D. WEBB
510(k) history	17 submissions · 16 cleared · 2011-2022

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k112493/> 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 27, 2026