

**K150294 DPZ Pedicular Fixation System**Jun 5, 2015  
119 days to decisionK150294 · Product code: **MNI** · Orthopedic  
Source: <https://www.510kdatabase.net/k150294/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Spinal Pedicle Fixation (MNI)
Date received	Feb 6, 2015
Decision date	Jun 5, 2015
Days to decision	119 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Osteomed Implantex, Ltda</b>
Location	Rio Claro - Sp, BR
Contact	J. D. Webb
510(k) history	3 submissions · 3 cleared · 2015-2016

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k150294/> 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