

**K110283 ZENIUS SPINAL SYSTEM**May 19, 2011  
107 days to decisionK110283 · Product code: **MNI** · Orthopedic  
Source: <https://www.510kdatabase.net/k110283/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthosis, Spinal Pedicle Fixation (MNI)
Date received	Feb 1, 2011
Decision date	May 19, 2011
Days to decision	107 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Medyssey Co, Ltd.</b>
Location	Santa Fe Springs, CA, US
Contact	PATRICK MOORE
510(k) history	11 submissions · 11 cleared · 2009-2025

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k110283/> 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