

K133103 AVERSION PEDICLE SCREW SYSTEMJan 27, 2014
119 days to decisionK133103 · Product code: **MNI** · Orthopedic
Source: <https://www.510kdatabase.net/k133103/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Spinal Pedicle Fixation (MNI)
Date received	Sep 30, 2013
Decision date	Jan 27, 2014
Days to decision	119 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	K7, LLC
Location	Chesterland, OH, US
Contact	KAREN E WARDEN
510(k) history	3 submissions · 3 cleared · 2013-2014

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k133103/> Data sourced from FDA 510(k) public records (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. - Generated May 17, 2026