

K111940 S 100 PEDICLE SCREW SYSTEMMay 15, 2012
312 days to decisionK111940 · Product code: **MNH** · Orthopedic
Source: <https://www.510kdatabase.net/k111940/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthosis, Spondylolisthesis Spinal Fixation (MNH)
Date received	Jul 8, 2011
Decision date	May 15, 2012
Days to decision	312 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Renovis Surgical Technologies, LLC
Location	Round Rock, TX, US
Contact	J.D. WEBB
510(k) history	9 submissions · 9 cleared · 2010-2014

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k111940/> 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