FDA 510(k) Premarket Notification

K111940 S 100 PEDICLE SCREW SYSTEM

CLEARED

May 15, 2012
312 days to decision

K111940 · 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