FDA 510(k) Premarket Notification

K130863 FACET SCREW SYSTEM

CLEARED

Aug 9, 2013
134 days to decision

K130863 · Product code: **MRW** · Orthopedic
Source: https://www.510kdatabase.net/k130863/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Facet Screw Spinal Device (MRW)
Date received	Mar 28, 2013
Decision date	Aug 9, 2013
Days to decision	134 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Spinal USA**
Location	Brandon, MS, US
Contact	JANICE M HOGAN
510(k) history	23 submissions · 23 cleared · 2006-2013