FDA 510(k) Premarket Notification

K131417 FACET FIXX

CLEARED

Jul 12, 2013
57 days to decision

K131417 · Product code: **MRW** · Orthopedic
Source: https://www.510kdatabase.net/k131417/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Facet Screw Spinal Device (MRW)
Date received	May 16, 2013
Decision date	Jul 12, 2013
Days to decision	57 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Nexxt Spine, LLC**
Location	Chesterland, OH, US
Contact	KAREN E WARDEN PHD
510(k) history	22 submissions · 22 cleared · 2009-2023