FDA 510(k) Premarket Notification

K101762 VIPER F2 FACET FIXATION SYSTEM

CLEARED

Nov 15, 2010
146 days to decision

K101762 · Product code: **MRW** · Orthopedic
Source: https://www.510kdatabase.net/k101762/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Facet Screw Spinal Device (MRW)
Date received	Jun 22, 2010
Decision date	Nov 15, 2010
Days to decision	146 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Depuy Spine, Inc.**
Location	Raynham, MA, US
Contact	FRANK JURCZAK
510(k) history	68 submissions · 67 cleared · 2004-2020