FDA 510(k) Premarket Notification

K142213 VIA SPINOUS PROCESS FIXATION SYSTEM

CLEARED

Sep 10, 2014
29 days to decision

K142213 · Product code: **PEK** · Orthopedic
Source: https://www.510kdatabase.net/k142213/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Spinous Process Plate (PEK)
Date received	Aug 12, 2014
Decision date	Sep 10, 2014
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Spineology, Inc.**
Location	Stillwater, MN, US
Contact	TIM CRABTREE
510(k) history	54 submissions · 51 cleared · 1999-2025