FDA 510(k) Premarket Notification

K121924 INTEGRA INTERSPINOUS PROCESS SYSTEM

CLEARED

Sep 4, 2013
429 days to decision

K121924 · Product code: **PEK** · Orthopedic
Source: https://www.510kdatabase.net/k121924/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spinous Process Plate (PEK)
Date received	Jul 2, 2012
Decision date	Sep 4, 2013
Days to decision	429 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Seaspine, Inc.**
Location	Vista, CA, US
Contact	NICK M CORDARO
510(k) history	27 submissions · 27 cleared · 2005-2023