FDA 510(k) Premarket Notification

CLEARED

K133418 INTEGRA EXPANDABLE INTERVEREBRAL BODY FUSION DEVICE (IBD) SYSTEM

May 1, 2014
175 days to decision

K133418 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k133418/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Nov 7, 2013
Decision date	May 1, 2014
Days to decision	175 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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