FDA 510(k) Premarket Notification

K151581 Leva Spacer System

CLEARED

Jul 9, 2015
28 days to decision

K151581 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k151581/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jun 11, 2015
Decision date	Jul 9, 2015
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Spine Wave, Inc.**
Location	Shelton, CT, US
Contact	GAIL YAEKER-DAUNIS
510(k) history	57 submissions · 57 cleared · 2004-2025