FDA 510(k) Premarket Notification

K132053 RAMPART-O, RAMPART-T

CLEARED

Sep 16, 2013
75 days to decision

K132053 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k132053/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jul 3, 2013
Decision date	Sep 16, 2013
Days to decision	75 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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