FDA 510(k) Premarket Notification

CLEARED

K121129 SPINEOLOGY PEEK LUMBAR INTERBODY FUSION DEVICE

Jun 13, 2012
61 days to decision

K121129 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k121129/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Apr 13, 2012
Decision date	Jun 13, 2012
Days to decision	61 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