FDA 510(k) Premarket Notification

CLEARED

K113030 SPINEOLOGY PEEK BULLET LUMBAR INTERBODY FUSION DEVICE

Jan 26, 2012
106 days to decision

K113030 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k113030/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Oct 12, 2011
Decision date	Jan 26, 2012
Days to decision	106 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