FDA 510(k) Premarket Notification

K111880 SPINEOLGY PEEK BULLET LUMBER INTERBODY FUSION DEVICE

CLEARED

Sep 26, 2011
87 days to decision

K111880 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k111880/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jul 1, 2011
Decision date	Sep 26, 2011
Days to decision	87 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