FDA 510(k) Premarket Notification

K190055 Duo Lumbar Interbody Fusion Device

CLEARED

Mar 7, 2019
55 days to decision

K190055 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k190055/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jan 11, 2019
Decision date	Mar 7, 2019
Days to decision	55 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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