FDA 510(k) Premarket Notification

K181792 Duo™ Lumbar Interbody Fusion Device

CLEARED

Aug 14, 2018
40 days to decision

K181792 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k181792/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jul 5, 2018
Decision date	Aug 14, 2018
Days to decision	40 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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