FDA 510(k) Premarket Notification

K160074 Rampart D Lumbar Interbody Fusion Device

CLEARED

Oct 18, 2016
278 days to decision

K160074 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k160074/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jan 14, 2016
Decision date	Oct 18, 2016
Days to decision	278 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