FDA 510(k) Premarket Notification

CLEARED

K160906 Rampart O Lumbar Interbody Fusion Device, Rampart T Lumbar Interbody Fusion Device, Rampart A lumbar Interbody Fusion Device

Jul 14, 2016
104 days to decision

K160906 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k160906/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Apr 1, 2016
Decision date	Jul 14, 2016
Days to decision	104 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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