FDA 510(k) Premarket Notification

K163670 Rampart One Lumbar Interbody Fusion Device

CLEARED

May 8, 2017
132 days to decision

K163670 · Product code: **OVD** · Orthopedic
Source: https://www.510kdatabase.net/k163670/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Lumbar (OVD)
Date received	Dec 27, 2016
Decision date	May 8, 2017
Days to decision	132 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