FDA 510(k) Premarket Notification

K171660 Duo Lumbar Interbody Fusion Device

CLEARED

Aug 18, 2017
74 days to decision

K171660 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k171660/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jun 5, 2017
Decision date	Aug 18, 2017
Days to decision	74 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