FDA 510(k) Premarket Notification

K133126 K7 LUMBAR SPACERS

CLEARED

Dec 9, 2013
70 days to decision

K133126 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k133126/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Sep 30, 2013
Decision date	Dec 9, 2013
Days to decision	70 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**K7, LLC**
Location	Chesterland, OH, US
Contact	KAREN E WARDEN, PHD
510(k) history	3 submissions · 3 cleared · 2013-2014