FDA 510(k) Premarket Notification

K113527 OPTICAGE INTERBODY FUSION DEVICE

CLEARED

Jan 20, 2012
51 days to decision

K113527 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k113527/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Nov 30, 2011
Decision date	Jan 20, 2012
Days to decision	51 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Interventional Spine, Inc.**
Location	Irvine, CA, US
Contact	JANE METCALF
510(k) history	8 submissions · 7 cleared · 2008-2016