FDA 510(k) Premarket Notification

K140716 OPTICAGE EXPANDABLE INTERBODY FUSION DEVICE

CLEARED

Nov 24, 2014
248 days to decision

K140716 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k140716/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Mar 21, 2014
Decision date	Nov 24, 2014
Days to decision	248 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