FDA 510(k) Premarket Notification

K160464 Opticage(R) Expandable Interbody Fusion Device

CLEARED

Apr 4, 2016
45 days to decision

K160464 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k160464/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Feb 19, 2016
Decision date	Apr 4, 2016
Days to decision	45 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