FDA 510(k) Premarket Notification

K132479 OPTICAGE INTERBODY FUSION DEVICE, MODEL 9080-00

CLEARED

Sep 19, 2013
42 days to decision

K132479 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k132479/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Aug 8, 2013
Decision date	Sep 19, 2013
Days to decision	42 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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