FDA 510(k) Premarket Notification

K133184 ARDIS INTERBODY SYSTEM

CLEARED

Jan 30, 2014
105 days to decision

K133184 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k133184/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Oct 17, 2013
Decision date	Jan 30, 2014
Days to decision	105 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Zimmer Spine, Inc.**
Location	Minneapolis, MN, US
Contact	MICHELLE LENZ
510(k) history	38 submissions · 35 cleared · 2004-2016