FDA 510(k) Premarket Notification

K110327 LDR SPINE ROI-A INTERBODY FUSION SYSTEM

CLEARED

Sep 30, 2011
239 days to decision

K110327 · Product code: **OVD** · Orthopedic
Source: https://www.510kdatabase.net/k110327/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Integrated Fixation, Lumbar (OVD)
Date received	Feb 3, 2011
Decision date	Sep 30, 2011
Days to decision	239 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ldr Spine USA**
Location	Austin, TX, US
Contact	MARITZA ELIAS
510(k) history	25 submissions · 25 cleared · 2005-2016