FDA 510(k) Premarket Notification

CLEARED

K153495 Avenue L Lateral Lumbar Cage, Avenue T TLIF Cage System, ROI-A ALIF Cage System, ROI-T Implant System

Mar 31, 2016
115 days to decision

K153495 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k153495/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Dec 7, 2015
Decision date	Mar 31, 2016
Days to decision	115 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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