FDA 510(k) Premarket Notification

K082262 LDR SPINE ROI INTERBODY FUSION SYSTEM

CLEARED

Feb 2, 2009
178 days to decision

K082262 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k082262/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Aug 8, 2008
Decision date	Feb 2, 2009
Days to decision	178 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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