FDA 510(k) Premarket Notification

K080569 LDR SPINE ROI-T IMPLANT

CLEARED

May 7, 2008
68 days to decision

K080569 · Product code: **MQP** · Orthopedic
Source: https://www.510kdatabase.net/k080569/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Spinal Vertebral Body Replacement Device (MQP)
Date received	Feb 29, 2008
Decision date	May 7, 2008
Days to decision	68 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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