FDA 510(k) Premarket Notification

K063794 MODIFICATION TO EASYSPINE SYSTEM

CLEARED

Jan 24, 2007
33 days to decision

K063794 · Product code: **MNI** · Orthopedic
Source: https://www.510kdatabase.net/k063794/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthosis, Spinal Pedicle Fixation (MNI)
Date received	Dec 22, 2006
Decision date	Jan 24, 2007
Days to decision	33 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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