FDA 510(k) Premarket Notification

K121567 ORACLE LUMBAR INTERVERTEBRAL BODY FUSION CAGE SYSTEM

CLEARED

Sep 26, 2012
120 days to decision

K121567 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k121567/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	May 29, 2012
Decision date	Sep 26, 2012
Days to decision	120 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Accel Spine**
Location	Dallas, TX, US
Contact	DANIEL CHON
510(k) history	10 submissions · 10 cleared · 2012-2014

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k121567/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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