FDA 510(k) Premarket Notification

K123100 INTESS LUMBAR CAGE

CLEARED

Mar 28, 2013
177 days to decision

K123100 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k123100/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Oct 2, 2012
Decision date	Mar 28, 2013
Days to decision	177 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Kalitec Direct, LLC**
Location	Round Rock, TX, US
Contact	J D WEBB
510(k) history	9 submissions · 9 cleared · 2011-2018

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k123100/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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