FDA 510(k) Premarket Notification

K092901 EPICAGE INTERBODY FUSION DEVICE

CLEARED

Apr 28, 2010
219 days to decision

K092901 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k092901/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Sep 21, 2009
Decision date	Apr 28, 2010
Days to decision	219 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**R Tree Innovations**
Location	Apple Valley, MN, US
Contact	RICHARD JANSEN
510(k) history	1 submissions · 1 cleared · 2010-2010