FDA 510(k) Premarket Notification

CLEARED

K122956 FUSELOX LUMBAR INTERBODY FUSION DEVICE

Oct 25, 2012
30 days to decision

K122956 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k122956/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Sep 25, 2012
Decision date	Oct 25, 2012
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Captiva Spine**
Location	Apple Valley, MN, US
Contact	RICH JANSEN
510(k) history	7 submissions · 7 cleared · 2012-2016