FDA 510(k) Premarket Notification

K092017 PIVOTEC LUMBAR INTERBODY FUSION DEVICE (LIFD)

CLEARED

Dec 1, 2009
148 days to decision

K092017 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k092017/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jul 6, 2009
Decision date	Dec 1, 2009
Days to decision	148 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Captiva Spine, Inc.**
Location	Pleasant Grove, UT, US
Contact	MIKE ENSIGN
510(k) history	8 submissions · 8 cleared · 2009-2020