FDA 510(k) Premarket Notification

CLEARED

K181531 SpineEX Sagittae Lateral Lumbar Interbody Fusion Devices

Oct 5, 2018
116 days to decision

K181531 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k181531/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jun 11, 2018
Decision date	Oct 5, 2018
Days to decision	116 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Spineex, Inc.**
Location	Fremont, CA, US
Contact	Andrew Rogers
510(k) history	3 submissions · 3 cleared · 2018-2020

REGULATORY CONSULTANT

Consulting firm	**Empirical Testing Corp**
Contact	Meredith Lee May

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov