FDA 510(k) Premarket Notification

CLEARED

K200816 SpineEX Sagittae Lateral Lumbar Interbody Fusion Devices

Apr 30, 2020
31 days to decision

K200816 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k200816/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Mar 30, 2020
Decision date	Apr 30, 2020
Days to decision	31 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	Nathan Wright

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