FDA 510(k) Premarket Notification

K211845 Deploy Expandable Interbody System

CLEARED

Nov 16, 2021
154 days to decision

K211845 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k211845/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jun 15, 2021
Decision date	Nov 16, 2021
Days to decision	154 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Southern Spine, LLC**
Location	Alpharetta, GA, US
Contact	Calder Clay
510(k) history	4 submissions · 4 cleared · 2007-2021

REGULATORY CONSULTANT

Consulting firm	**Regulatory Resources Group, Inc.**
Contact	Julie Stephens

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