FDA 510(k) Premarket Notification

K192248 Cortina™ [MAX] Lumbar Cage System

CLEARED

Nov 25, 2019
98 days to decision

K192248 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k192248/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Aug 19, 2019
Decision date	Nov 25, 2019
Days to decision	98 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Neurostructures, Inc.**
Location	Colorado Springs, CO, US
Contact	Moti Altarac
510(k) history	15 submissions · 15 cleared · 2014-2020

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