FDA 510(k) Premarket Notification

K201769 Cavetto [MAX] Cervical Cage System

CLEARED

Sep 3, 2020
66 days to decision

K201769 · Product code: **ODP** · Orthopedic
Source: https://www.510kdatabase.net/k201769/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Jun 29, 2020
Decision date	Sep 3, 2020
Days to decision	66 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	Nathan Wright

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