FDA 510(k) Premarket Notification

CLEARED

K202190 Oculus-SA Lumbar Cage System

Oct 2, 2020
58 days to decision

K202190 · Product code: **OVD** · Orthopedic
Source: https://www.510kdatabase.net/k202190/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Lumbar (OVD)
Date received	Aug 5, 2020
Decision date	Oct 2, 2020
Days to decision	58 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Neurostructures**
Location	Irvine, CA, US
Contact	Moti Altarac
510(k) history	1 submissions · 1 cleared · 2020-2020

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