FDA 510(k) Premarket Notification

CLEARED

K211769 OneLIF Intervertebral Body Replacement System

Sep 7, 2021
91 days to decision

K211769 · Product code: **OVD** · Orthopedic
Source: https://www.510kdatabase.net/k211769/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Lumbar (OVD)
Date received	Jun 8, 2021
Decision date	Sep 7, 2021
Days to decision	91 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Novapproach Spine**
Location	Alachua, FL, US
Contact	Ronald P. Green
510(k) history	1 submissions · 1 cleared · 2021-2021

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