FDA 510(k) Premarket Notification

CLEARED

K203129 NexGen Standalone Anterior Cervical Discectomy and Fusion (ACDF) System

Jan 12, 2021
85 days to decision

K203129 · Product code: **OVE** · Orthopedic
Source: https://www.510kdatabase.net/k203129/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	Oct 19, 2020
Decision date	Jan 12, 2021
Days to decision	85 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Precision Spine, Inc.**
Location	Pear, MS, US
Contact	Michael Dawson
510(k) history	24 submissions · 24 cleared · 2014-2025

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k203129/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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