FDA 510(k) Premarket Notification

K192494 NexGen Anterior Cervical Plate System

CLEARED

Oct 29, 2019
48 days to decision

K192494 · Product code: **KWQ** · Orthopedic
Source: https://www.510kdatabase.net/k192494/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Sep 11, 2019
Decision date	Oct 29, 2019
Days to decision	48 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Precision Spine**
Location	Pear, MS, US
Contact	Michael C. Dawson
510(k) history	2 submissions · 2 cleared · 2019-2020

REGULATORY CONSULTANT

Consulting firm	**The OrthoMedix Group, Inc.**
Contact	J. D. Webb

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