FDA 510(k) Premarket Notification

K202192 STRUXXURE®-L and STRUXXURE®-A Plate System

CLEARED

Sep 17, 2020
43 days to decision

K202192 · Product code: **KWQ** · Orthopedic
Source: https://www.510kdatabase.net/k202192/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Aug 5, 2020
Decision date	Sep 17, 2020
Days to decision	43 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Nexxt Spine, LLC**
Location	Chesterland, OH, US
Contact	Andy Elsbury
510(k) history	22 submissions · 22 cleared · 2009-2023

REGULATORY CONSULTANT

Consulting firm	**Backroads Consulting**
Contact	Karen E. Warden

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