FDA 510(k) Premarket Notification

K200170 SpineNet SSP System

CLEARED

Feb 5, 2020
13 days to decision

K200170 · Product code: **KWQ** · Orthopedic
Source: https://www.510kdatabase.net/k200170/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Jan 23, 2020
Decision date	Feb 5, 2020
Days to decision	13 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Spinenet, LLC**
Location	Round Rock, TX, US
Contact	King Floyd
510(k) history	2 submissions · 2 cleared · 2011-2020

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