FDA 510(k) Premarket Notification

K213266 Inspan ScrewLES Fusion System

CLEARED

Dec 3, 2021
64 days to decision

K213266 · Product code: **PEK** · Orthopedic
Source: https://www.510kdatabase.net/k213266/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spinous Process Plate (PEK)
Date received	Sep 30, 2021
Decision date	Dec 3, 2021
Days to decision	64 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Lespine Innovations, LLC**
Location	Malden, MA, US
Contact	John Sullivan
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	**MRCA, LLC**
Contact	Justin Eggleton

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