

K213266 Inspan ScrewLES Fusion SystemDec 3, 2021
64 days to decisionK213266 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213266/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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