

K212075 ShurFit Lumbar Interbody SystemDec 8, 2021
159 days to decisionK212075 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k212075/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jul 2, 2021
Decision date	Dec 8, 2021
Days to decision	159 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Precision Spine, Inc.
Location	Pear, MS, US
Contact	Michael Dawson
510(k) history	24 submissions · 24 cleared · 2014-2025

REGULATORY CONSULTANT

Consulting firm	Empirical Testing Corp
Contact	Nathan Wright

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/k212075/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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