

K213951 FORZA XP Expandable Spacer SystemJan 5, 2022
19 days to decisionK213951 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k213951/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Dec 17, 2021
Decision date	Jan 5, 2022
Days to decision	19 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Orthofix US, LLC
Location	Lweisville, TX, US
Contact	Natalia Volosen
510(k) history	4 submissions · 4 cleared · 2022-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213951/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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