

K191791 Trans1 Interbody Fusion SystemSep 25, 2019
84 days to decisionK191791 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k191791/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jul 3, 2019
Decision date	Sep 25, 2019
Days to decision	84 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Trans1
Location	Wilmington, NC, US
Contact	Kristen Allen
510(k) history	2 submissions · 2 cleared · 2019-2019

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