

K192792 TranS1 AxiaLIF Plus SystemNov 20, 2019
51 days to decisionK192792 · Product code: **KWQ** · Orthopedic
Source: <https://www.510kdatabase.net/k192792/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Sep 30, 2019
Decision date	Nov 20, 2019
Days to decision	51 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k192792/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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