

K200927 Transept Cervical Plate SystemJul 24, 2020
108 days to decisionK200927 · Product code: **KWQ** · Orthopedic
Source: <https://www.510kdatabase.net/k200927/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Apr 7, 2020
Decision date	Jul 24, 2020
Days to decision	108 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Neurostructures, Inc.
Location	Colorado Springs, CO, US
Contact	Moti Altarac
510(k) history	15 submissions · 15 cleared · 2014-2020

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/k200927/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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