

K220843 OAKTREE Anterior Lumbar Plate and Screw SystemDec 7, 2022
259 days to decisionK220843 · Product code: **KWQ** · Orthopedic
Source: <https://www.510kdatabase.net/k220843/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Mar 23, 2022
Decision date	Dec 7, 2022
Days to decision	259 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Oak Tree Engineering, LLC
Location	Huntington Beach, CA, US
Contact	Douglas W. Neary
510(k) history	2 submissions · 2 cleared · 2021-2022

REGULATORY CONSULTANT

Consulting firm	Consultant
Contact	Douglas W. Neary

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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