

**K211932 Fixxsure Anterior Lumbar Plate and Screw System**Jul 27, 2021  
35 days to decisionK211932 · Product code: **KWQ** · Orthopedic  
Source: <https://www.510kdatabase.net/k211932/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Jun 22, 2021
Decision date	Jul 27, 2021
Days to decision	35 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Consultant</b>
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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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k211932/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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