

K221795 STERN FIX Sternal Stabilization SystemOct 19, 2022
120 days to decisionK221795 · Product code: **JDQ** · Orthopedic
Source: <https://www.510kdatabase.net/k221795/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cerclage, Fixation (JDQ)
Date received	Jun 21, 2022
Decision date	Oct 19, 2022
Days to decision	120 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Neos Surgery S.L
Location	Alexandria, VA, US
Contact	Eduard Garcia Puig
510(k) history	6 submissions · 6 cleared · 2010-2024

REGULATORY CONSULTANT

Consulting firm	Msquared Associates, Inc.
Contact	Cherita James

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

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