

K211613 Stern Fix Sternal Stabilization SystemJan 19, 2022
238 days to decisionK211613 · Product code: **JDQ** · Orthopedic
Source: <https://www.510kdatabase.net/k211613/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cerclage, Fixation (JDQ)
Date received	May 26, 2021
Decision date	Jan 19, 2022
Days to decision	238 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211613/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026