

K211323 ASTRA Spine SystemJun 3, 2021
34 days to decisionK211323 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k211323/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Apr 30, 2021
Decision date	Jun 3, 2021
Days to decision	34 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Spinecraft, LLC
Location	Westchester, IL, US
Contact	Ami Akallal-Asaad
510(k) history	12 submissions · 12 cleared · 2010-2023

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