

K212066 Adena-Zina SystemAug 16, 2021
45 days to decisionK212066 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k212066/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Jul 2, 2021
Decision date	Aug 16, 2021
Days to decision	45 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shanghai Sanyou Medical Co, Ltd.
Location	Bartlett, TN, US
Contact	David Fan
510(k) history	9 submissions · 9 cleared · 2013-2023

REGULATORY CONSULTANT

Consulting firm	MRC Global, LLC
Contact	Christine Scifert

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

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