

K210306 GII Spinal Fixation SystemMay 19, 2021
105 days to decisionK210306 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k210306/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Feb 3, 2021
Decision date	May 19, 2021
Days to decision	105 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Coligne AG
Location	Zurich, CH
Contact	Robert B Lange
510(k) history	4 submissions · 4 cleared · 2017-2021

REGULATORY CONSULTANT

Consulting firm	The OrthoMedix Group, Inc.
Contact	J.D. Webb

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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