

K210539 CoreLink Midline Fixation SystemApr 15, 2021
50 days to decisionK210539 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k210539/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Thoracolumbosacral Pedicle Screw System (NKB) |
| Date received | Feb 24, 2021 |
| Decision date | Apr 15, 2021 |
| Days to decision | 50 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Corelink, LLC |
| Location | Round Rock, TX, US |
| Contact | Steven Mounts |
| 510(k) history | 35 submissions · 35 cleared · 2008-2023 |

REGULATORY CONSULTANT

| | |
|-----------------|-------------------------------|
| Consulting firm | Empirical Testing Corp |
| Contact | Nathan Wright |

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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