

K202498 4CIS SARA Spine System, 4CIS VERTU Spine SystemFeb 18, 2021
171 days to decisionK202498 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k202498/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Aug 31, 2020
Decision date	Feb 18, 2021
Days to decision	171 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Solco Biomedical Company India Private Limited
Location	Village-Rajpur, IN
Contact	Viral Sheth
510(k) history	2 submissions · 2 cleared · 2021-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k202498/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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