

K201427 Trivergent Spinal Fixation SystemOct 21, 2020
145 days to decisionK201427 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k201427/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	May 29, 2020
Decision date	Oct 21, 2020
Days to decision	145 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Benvenue Medical, Inc.
Location	Mountain View, CA, US
Contact	Laurent Schaller
510(k) history	8 submissions · 8 cleared · 2007-2020

REGULATORY CONSULTANT

Consulting firm	Mcra, LLC
Contact	Justin Eggleston

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k201427/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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