

K210816 True Tulip, True M.I.S.May 18, 2021
61 days to decisionK210816 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k210816/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Mar 18, 2021
Decision date	May 18, 2021
Days to decision	61 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Innovative Surgical Designs, Inc.
Location	Bloomington, IN, US
Contact	Jon Rinehart
510(k) history	7 submissions · 7 cleared · 2017-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k210816/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026