

K190600 ORION Spinal SystemAug 18, 2020
529 days to decisionK190600 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k190600/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Mar 8, 2019
Decision date	Aug 18, 2020
Days to decision	529 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Orion Biotech, Inc.
Location	Taipei, TW
Contact	Yuki Chen
510(k) history	1 submissions · 1 cleared · 2020-2020

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