

K191494 Facilis™ Spinal SystemAug 12, 2019
68 days to decisionK191494 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k191494/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Jun 5, 2019
Decision date	Aug 12, 2019
Days to decision	68 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Baui Biotech Co., Ltd.
Location	New Taipei City, TW
Contact	Herman Jhan
510(k) history	5 submissions · 5 cleared · 2017-2024

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