

K161231 Facilis™ Spinal SystemJan 23, 2017
266 days to decisionK161231 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k161231/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	May 2, 2016
Decision date	Jan 23, 2017
Days to decision	266 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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