

K192121 Black Diamond Pedicle Screw SystemOct 29, 2019
84 days to decisionK192121 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k192121/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Aug 6, 2019
Decision date	Oct 29, 2019
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Osseus Fusion Systems
Location	Dallas, TX, US
Contact	Robert Pace
510(k) history	5 submissions · 5 cleared · 2019-2023

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