

K160640 PASS XS Spinal SystemSep 23, 2016
200 days to decisionK160640 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k160640/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Mar 7, 2016
Decision date	Sep 23, 2016
Days to decision	200 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medicrea International SA
Location	Neyron, FR
Contact	David Ryan
510(k) history	25 submissions · 25 cleared · 2015-2022

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