

K172101 ROMEO® 2 Posterior Osteosynthesis SystemSep 26, 2017
76 days to decisionK172101 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k172101/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Jul 12, 2017
Decision date	Sep 26, 2017
Days to decision	76 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Spineart
Location	Geneva, CH
Contact	Franck Pennesi
510(k) history	44 submissions · 44 cleared · 2008-2023

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