

K191726 mont blanc & mont blanc MIS Spinal SystemsSep 12, 2019
77 days to decisionK191726 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k191726/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Jun 27, 2019
Decision date	Sep 12, 2019
Days to decision	77 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Spineway SA
Location	Ecully, FR
Contact	Heloise Macaire
510(k) history	2 submissions · 2 cleared · 2016-2019

REGULATORY CONSULTANT

Consulting firm	Novus Management Group, LLC
Contact	Tamala J. Wampler

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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