

K201648 Sterispine™ PSJul 30, 2020
42 days to decisionK201648 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k201648/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Jun 18, 2020
Decision date	Jul 30, 2020
Days to decision	42 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Safe Orthopaedics
Location	Eragny Sur Oise, FR
Contact	Pierre Dumouchel
510(k) history	13 submissions · 13 cleared · 2011-2020

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