

K211981 KHEIRON® Spinal Fixation SystemJun 9, 2022
349 days to decisionK211981 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k211981/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Jun 25, 2021
Decision date	Jun 9, 2022
Days to decision	349 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	S.M.A.I.O
Location	Saint-Priest, FR
Contact	Jean-Charles Roussouly
510(k) history	10 submissions · 10 cleared · 2020-2026

REGULATORY CONSULTANT

Consulting firm	The OrthoMedix Group, Inc.
Contact	J.D. Webb

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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