

K201659 KHEIRON® Spinal Fixation SystemOct 5, 2020
109 days to decisionK201659 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k201659/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Jun 18, 2020
Decision date	Oct 5, 2020
Days to decision	109 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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