

K253721 KHEIRON® Spinal Fixation System, including patient specific K-RODDec 17, 2025
23 days to decisionK253721 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k253721/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Nov 24, 2025
Decision date	Dec 17, 2025
Days to decision	23 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	BioVera, Inc.
Contact	Robert A Poggie

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k253721/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026