

**K260786 KHEIRON® Spinal Fixation System, including patient specific K-ROD**Apr 3, 2026  
24 days to decisionK260786 · Product code: **NKB** · Orthopedic  
Source: <https://www.510kdatabase.net/k260786/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Mar 10, 2026
Decision date	Apr 3, 2026
Days to decision	24 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>BioVera, Inc.</b>
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)

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