

**K253118 Companion Spine DIAM™ Instrumentation**Dec 16, 2025  
83 days to decisionK253118 · Product code: **QLR** · Orthopedic  
Source: <https://www.510kdatabase.net/k253118/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Manual Instruments Designed For Use With Non-fusion Spinous Process Spacer Devices (QLR)
Date received	Sep 24, 2025
Decision date	Dec 16, 2025
Days to decision	83 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Companion Spine France</b>
Location	M?rignac, FR
Contact	Nazanine Cloix
510(k) history	1 submissions · 1 cleared · 2025-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Mcra, LLC</b>
Contact	Lucas Tatem

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k253118/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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