

**K251629 UNiD™ Spine Analyzer**Aug 7, 2025  
71 days to decisionK251629 · Product code: **QIH** · Radiology  
Source: <https://www.510kdatabase.net/k251629/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	May 28, 2025
Decision date	Aug 7, 2025
Days to decision	71 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medicrea International S.A.S. (Medtronic)</b>
Location	Rillieux-La-Pape, FR
Contact	Cecile Humbert
510(k) history	3 submissions · 3 cleared · 2024-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k251629/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 14, 2026