

**K212005 UNiD Spine Analyzer**Jan 12, 2022  
198 days to decisionK212005 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k212005/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jun 28, 2021
Decision date	Jan 12, 2022
Days to decision	198 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medicrea International, Inc.</b>
Location	Rilleux La Pape, FR
Contact	David Ryan
510(k) history	1 submissions · 1 cleared · 2022-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>Sterling Medical Devices</b>
Contact	Teal Bjoraker

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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