

K261289 UNiD™ Spine Analyzer (SW3002)May 15, 2026
25 days to decisionK261289 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k261289/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Apr 20, 2026
Decision date	May 15, 2026
Days to decision	25 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medicrea International S.A.S. (Medtronic)
Location	Rillieux-La-Pape, FR
Contact	Hajar BOULMAN
510(k) history	4 submissions · 4 cleared · 2024-2026

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