FDA 510(k) Premarket Notification

K251629 UNiD™ Spine Analyzer

CLEARED

Aug 7, 2025
71 days to decision

K251629 · Product code: **QIH** · Radiology
Source: https://www.510kdatabase.net/k251629/

SUBMISSION DETAILS

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

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