FDA 510(k) Premarket Notification

K212005 UNiD Spine Analyzer

CLEARED

Jan 12, 2022
198 days to decision

K212005 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k212005/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**Sterling Medical Devices**
Contact	Teal Bjoraker

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