

K212291 PHOENIXSep 14, 2021
54 days to decisionK212291 · Product code: **IZL** · Radiology
Source: <https://www.510kdatabase.net/k212291/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Mobile (IZL)
Date received	Jul 22, 2021
Decision date	Sep 14, 2021
Days to decision	54 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sedecal., Sa.
Location	Deer Field, IL, US
Contact	M ^a Luisa Gómez de Agüero
510(k) history	26 submissions · 26 cleared · 2002-2023

REGULATORY CONSULTANT

Consulting firm	Kamm & Associates
Contact	Daniel Kamm

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212291/> Data sourced from FDA 510(k) public records (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. - Generated May 13, 2026