

K222951 SM-VNov 21, 2022
55 days to decisionK222951 · Product code: **IZL** · Radiology
Source: <https://www.510kdatabase.net/k222951/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	System, X-ray, Mobile (IZL)
Date received	Sep 27, 2022
Decision date	Nov 21, 2022
Days to decision	55 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.gov](https://accessdata.fda.gov)

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