

K232185 SM-IVAug 21, 2023
28 days to decisionK232185 · Product code: **IZL** · Radiology
Source: <https://www.510kdatabase.net/k232185/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, X-ray, Mobile (IZL)
Date received	Jul 24, 2023
Decision date	Aug 21, 2023
Days to decision	28 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

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