

K161345 RadPRO® Mobile 40kWJul 6, 2016
54 days to decisionK161345 · Product code: **IZL** · Radiology
Source: <https://www.510kdatabase.net/k161345/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, X-ray, Mobile (IZL)
Date received	May 13, 2016
Decision date	Jul 6, 2016
Days to decision	54 days
Third-party review	No
Summary / Statement	Summary
Other names	RadPRO® Mobile 40kW FLEXPLUS, Model SM-40HF-B-D-VIR

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k161345/>. 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 14, 2026