

**K203537 Proteus XR/f, Models ST and ET, Multirad and Multirad
NET Radiographic Systems**Feb 1, 2021
60 days to decisionK203537 · Product code: **KPR** · Radiology
Source: <https://www.510kdatabase.net/k203537/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	System, X-ray, Stationary (KPR)
Date received	Dec 3, 2020
Decision date	Feb 1, 2021
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sedecal., Sa.
Location	Deer Field, IL, US
Contact	Ma Luisa Gomez 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)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k203537/>; 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