FDA 510(k) Premarket Notification

CLEARED

K203537 Proteus XR/f, Models ST and ET, Multirad and Multirad NET Radiographic Systems

Feb 1, 2021
60 days to decision

K203537 · 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 Aguero
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