FDA 510(k) Premarket Notification

K193360 Acuity SDR Standard, Acuity SDR Plus, Acuity FDR Standard

CLEARED

Jan 2, 2020
29 days to decision

K193360 · Product code: **KPR** · Radiology
Source: https://www.510kdatabase.net/k193360/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Stationary (KPR)
Date received	Dec 4, 2019
Decision date	Jan 2, 2020
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Radmedix, LLC**
Location	Dayton, OH, US
Contact	Gabriel Issa
510(k) history	6 submissions · 6 cleared · 2020-2023