

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

Jan 2, 2020  
29 days to decision

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

**SUBMISSION DETAILS**

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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**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k193360/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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