

**K191504 PowerDR**Aug 16, 2019  
71 days to decisionK191504 · Product code: **JAA** · Radiology  
Source: <https://www.510kdatabase.net/k191504/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Fluoroscopic, Image-intensified (JAA)
Date received	Jun 6, 2019
Decision date	Aug 16, 2019
Days to decision	71 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Radiology Information Systems, Inc.</b>
Location	Crofton, MD, US
Contact	Chen-Tai Ma
510(k) history	3 submissions · 3 cleared · 1997-2019

**REGULATORY CONSULTANT**

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Consulting firm	<b>Kamm &amp; Associates</b>
Contact	Daniel Kamm

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k191504/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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