FDA 510(k) Premarket Notification

K191504 PowerDR

CLEARED

Aug 16, 2019
71 days to decision

K191504 · Product code: **JAA** · Radiology
Source: https://www.510kdatabase.net/k191504/

SUBMISSION DETAILS

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

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

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