FDA 510(k) Premarket Notification

K210919 AcuityDRe

CLEARED

Apr 30, 2021
32 days to decision

K210919 · Product code: **MQB** · Radiology
Source: https://www.510kdatabase.net/k210919/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Solid State X-ray Imager (flat Panel/digital Imager) (MQB)
Date received	Mar 29, 2021
Decision date	Apr 30, 2021
Days to decision	32 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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