

**K213691 Solas OR**Dec 22, 2021  
29 days to decisionK213691 · Product code: **MWP** · Radiology  
Source: <https://www.510kdatabase.net/k213691/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cabinet, X-ray System (MWP)
Date received	Nov 23, 2021
Decision date	Dec 22, 2021
Days to decision	29 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cirdan Imaging, Ltd.</b>
Location	Lisburn, GB
Contact	Paul Matthews
510(k) history	1 submissions · 1 cleared · 2021-2021

**REGULATORY CONSULTANT**

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Consulting firm	<b>Regulatory Technology Services, LLC</b>
Contact	Prithul Bom

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

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