

K193317 CoreLite X-Ray Specimen CabinetDec 13, 2019
14 days to decisionK193317 · Product code: **MWP** · Radiology
Source: <https://www.510kdatabase.net/k193317/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cabinet, X-ray System (MWP)
Date received	Nov 29, 2019
Decision date	Dec 13, 2019
Days to decision	14 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Cirdan Imaging Limited
Location	Lisburn, GB
Contact	Jenna McGarry
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	Regulatory Technology Services, LLC
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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