

**K201119 ChartCheck**Jun 26, 2020  
60 days to decisionK201119 · Product code: **IYE** · Radiology  
Source: <https://www.510kdatabase.net/k201119/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Apr 27, 2020
Decision date	Jun 26, 2020
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Radformation, Inc.</b>
Location	New York, NY, US
Contact	Kurt Sysock
Website	<a href="https://radformation.com">https://radformation.com</a>
510(k) history	14 submissions · 14 cleared · 2017-2026

Radformation, Inc. develops intelligent automation software for cancer care and radiation oncology. The company specializes in treatment planning, quality assurance, and clinical workflow optimization with a manufacturing facility in New York, US. Radformation has received FDA 510(k) clearances from total submissions, all in Radiology devices. The company's regulatory track record spans from 2017 to 2026, with its most recent clearance in 2026 demonstrating continued active development and market presence. The company's cleared portfolio includes automated contouring, tre...