

**K260509 AutoContour (RADAC V5)**Mar 19, 2026  
30 days to decisionK260509 · Product code: **QKB** · Radiology  
Source: <https://www.510kdatabase.net/k260509/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Radiological Image Processing Software For Radiation Therapy (QKB)
Date received	Feb 17, 2026
Decision date	Mar 19, 2026
Days to decision	30 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	Jennifer Wampler
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...