

K230685 AutoContour Model RADAC V3Apr 14, 2023
32 days to decisionK230685 · Product code: **QKB** · Radiology
Source: <https://www.510kdatabase.net/k230685/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Radiological Image Processing Software For Radiation Therapy (QKB)
Date received	Mar 13, 2023
Decision date	Apr 14, 2023
Days to decision	32 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Radformation, Inc.
Location	New York, NY, US
Contact	Kurt Sysock
Website	https://radformation.com
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...