FDA 510(k) Premarket Notification

K253962 ClearCheck (RADCC V2.7)

CLEARED

Apr 3, 2026
113 days to decision

K253962 · Product code: **IYE** · Radiology
Source: https://www.510kdatabase.net/k253962/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Dec 11, 2025
Decision date	Apr 3, 2026
Days to decision	113 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Radformation, Inc.**
Location	New York, NY, US
Contact	Jennifer Wampler
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...