FDA 510(k) Premarket Notification

K171350 Collision Check

CLEARED

Nov 29, 2017
204 days to decision

K171350 · Product code: **IYE** · Radiology
Source: https://www.510kdatabase.net/k171350/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	May 9, 2017
Decision date	Nov 29, 2017
Days to decision	204 days
Third-party review	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...