

K171352 EZFluenceDec 1, 2017
206 days to decisionK171352 · Product code: **IYE** · Radiology
Source: <https://www.510kdatabase.net/k171352/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Accelerator, Linear, Medical (IYE) |
| Date received | May 9, 2017 |
| Decision date | Dec 1, 2017 |
| Days to decision | 206 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...
