

K252071 Reflexion Medical Radiotherapy System, Reflexion X2Dec 18, 2025
170 days to decisionK252071 · Product code: **QVA** · Radiology
Source: <https://www.510kdatabase.net/k252071/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fludeoxyglucose F18-guided Radiation Therapy System (QVA)
Date received	Jul 1, 2025
Decision date	Dec 18, 2025
Days to decision	170 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Reflexion Medical, Inc.
Location	Hayward, CA, US
Contact	Leena Kadakia
510(k) history	3 submissions · 2 cleared · 2020-2025

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