FDA 510(k) Premarket Notification

K252296 OncoPatch

CLEARED

Dec 5, 2025
135 days to decision

K252296 · Product code: **KXK** · Radiology
Source: https://www.510kdatabase.net/k252296/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Source, Brachytherapy, Radionuclide (KXK)
Date received	Jul 23, 2025
Decision date	Dec 5, 2025
Days to decision	135 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Oncopatch, Inc.**
Location	Aurora, CO, US
Contact	Sam Murray
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	**TAMM Net, Inc.**
Contact	Sam Murray

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov