

K180515 GammaTileJul 6, 2018
129 days to decisionK180515 · Product code: **KXK** · Radiology
Source: <https://www.510kdatabase.net/k180515/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Source, Brachytherapy, Radionuclide (KXK)
Date received	Feb 27, 2018
Decision date	Jul 6, 2018
Days to decision	129 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Isoray Medical, Inc.
Location	Richland, WA, US
Contact	Bill Joy
510(k) history	5 submissions · 5 cleared · 2009-2020

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