FDA 510(k) Premarket Notification

K242818 IsoSphere

CLEARED

Jul 15, 2025
300 days to decision

K242818 · Product code: **KXK** · Radiology
Source: https://www.510kdatabase.net/k242818/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Source, Brachytherapy, Radionuclide (KXK)
Date received	Sep 18, 2024
Decision date	Jul 15, 2025
Days to decision	300 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Isoaid, LLC**
Location	Port Richey, FL, US
Contact	Timothy Bright
510(k) history	5 submissions · 5 cleared · 2004-2025