

**K242818 IsoSphere**Jul 15, 2025  
300 days to decisionK242818 · Product code: **KXK** · Radiology  
Source: <https://www.510kdatabase.net/k242818/>**SUBMISSION DETAILS**

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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**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k242818/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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