

**K214062 Radialis PET Camera**Feb 4, 2022  
39 days to decisionK214062 · Product code: **KPS** · Radiology  
Source: <https://www.510kdatabase.net/k214062/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Tomography, Computed, Emission (KPS)
Date received	Dec 27, 2021
Decision date	Feb 4, 2022
Days to decision	39 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Radialis, Inc.</b>
Location	Thunder Bay, CA
Contact	Michael Waterston
510(k) history	1 submissions · 1 cleared · 2022-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>Beanstock Consulting</b>
Contact	Eileen Heller

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k214062/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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