

**K210450 BBX-PET Scanner**Mar 17, 2021  
29 days to decisionK210450 · Product code: **KPS** · Radiology  
Source: <https://www.510kdatabase.net/k210450/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Tomography, Computed, Emission (KPS)
Date received	Feb 16, 2021
Decision date	Mar 17, 2021
Days to decision	29 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Prescient Imaging, LLC</b>
Location	Hawthorne, CA, US
Contact	Farhad Daghighian
510(k) history	1 submissions · 1 cleared · 2021-2021

**REGULATORY CONSULTANT**

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Consulting firm	<b>Third Party Review Group, LLC</b>
Contact	Dave Yungvirt

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/k210450/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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