

**K201933 ImagenSPECT 3.0**Aug 11, 2020  
29 days to decisionK201933 · Product code: **KPS** · Radiology  
Source: <https://www.510kdatabase.net/k201933/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Tomography, Computed, Emission (KPS)
Date received	Jul 13, 2020
Decision date	Aug 11, 2020
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cardiovascular Imaging Technologies</b>
Location	Lenexa, KS, US
Contact	James A. Case
510(k) history	4 submissions · 4 cleared · 2012-2020

**REGULATORY CONSULTANT**

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Consulting firm	<b>Pra Health Sciences</b>
Contact	Melanie Hasek

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

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