

K173547 ImagenUniversalJan 12, 2018
57 days to decisionK173547 · Product code: **KPS** · Radiology
Source: <https://www.510kdatabase.net/k173547/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Tomography, Computed, Emission (KPS)
Date received	Nov 16, 2017
Decision date	Jan 12, 2018
Days to decision	57 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Pra Health Sciences
Contact	Melanie K. 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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