FDA 510(k) Premarket Notification

K173547 ImagenUniversal

CLEARED

Jan 12, 2018
57 days to decision

K173547 · 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