FDA 510(k) Premarket Notification

K201933 ImagenSPECT 3.0

CLEARED

Aug 11, 2020
29 days to decision

K201933 · Product code: **KPS** · Radiology
Source: https://www.510kdatabase.net/k201933/

SUBMISSION DETAILS

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

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 Hasek

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