FDA 510(k) Premarket Notification

CLEARED

K201053 PercuNav Image Fusion and Interventional Navigation

May 14, 2020
23 days to decision

K201053 · Product code: **JAK** · Radiology
Source: https://www.510kdatabase.net/k201053/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Apr 21, 2020
Decision date	May 14, 2020
Days to decision	23 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Philips Ultrasound, Inc.**
Location	Santa Ana, CA, US
Contact	Travis Catania
510(k) history	46 submissions · 46 cleared · 1985-2021

REGULATORY CONSULTANT

Consulting firm	**Regulatory Technology Services, LLC**
Contact	Prithul Bom

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