FDA 510(k) Premarket Notification

CLEARED

K223804 PercuNav Image Fusion and Interventional Navigation System

Jan 18, 2023
30 days to decision

K223804 · Product code: **JAK** · Radiology
Source: https://www.510kdatabase.net/k223804/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Dec 19, 2022
Decision date	Jan 18, 2023
Days to decision	30 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Philips Ultrasound, LLC**
Location	Bothell, WA, US
Contact	Courtney Nix
510(k) history	20 submissions · 20 cleared · 2022-2026

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