

K223804 PercuNav Image Fusion and Interventional Navigation System

Jan 18, 2023
30 days to decisionK223804 · 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](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k223804/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026