CLEARED

Sep 27, 2022
26 days to decision

K222648 5000 Compact Series Ultrasound Systems (Ultrasound System 5500 G, Ultrasound System 5500 P, Ultrasound System 5500 W, Ultrasound System 5500 CV, Ultrasound System 5300 G, Ultrasound System 5300 P, Ultrasound System 5300 W)

K222648 · Product code: **IYN** · Radiology
Source: https://www.510kdatabase.net/k222648/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Sep 1, 2022
Decision date	Sep 27, 2022
Days to decision	26 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Philips Ultrasound, LLC**
Location	Bothell, WA, US
Contact	Shilpa Rapaka
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