FDA 510(k) Premarket Notification

K202216 EPIQ Series Diagnostic Ultrasound Systems

CLEARED

Sep 2, 2020
27 days to decision

K202216 · Product code: **IYN** · Radiology
Source: https://www.510kdatabase.net/k202216/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Aug 6, 2020
Decision date	Sep 2, 2020
Days to decision	27 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	Colin S. Jacob
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