FDA 510(k) Premarket Notification

CLEARED

K200304 EPIQ Diagnostic Ultrasound System

Mar 6, 2020
29 days to decision

K200304 · Product code: **IYN** · Radiology
Source: https://www.510kdatabase.net/k200304/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Feb 6, 2020
Decision date	Mar 6, 2020
Days to decision	29 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	Linda Schulz
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