FDA 510(k) Premarket Notification

CLEARED

K181485 EPIQ , EPIQ 5, EPIQ 7, Affiniti 30, Affiniti 50 and Affiniti 70 Diagnostic Ultrasound System

Jul 27, 2018
51 days to decision

K181485 · Product code: **IYN** · Radiology
Source: https://www.510kdatabase.net/k181485/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Jun 6, 2018
Decision date	Jul 27, 2018
Days to decision	51 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**Philips Ultrasound, Inc.**
Location	Santa Ana, CA, US
Contact	Kym Rupp
510(k) history	46 submissions · 46 cleared · 1985-2021

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k181485/ 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 26, 2026