

K182857 EPIQ Diagnostic Ultrasound System, EPIQ 5 Diagnostic Ultrasound System, EPIQ 7 Diagnostic Ultrasound System, Affiniti 30 Diagnostic Ultrasound System, Affiniti 50 Diagnostic Ultrasound System, Affiniti 70 Diagnostic Ultrasound System

Nov 9, 2018
30 days to decision

K182857 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k182857/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Oct 10, 2018
Decision date	Nov 9, 2018
Days to decision	30 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
