CLEARED

K160807 EPIQ 5 Diagnostic Ultrasound System, EPIQ 7Diagnostic Ultrasound System, Affiniti 50 Diagnostic Ultrasound System, Affiniti 70 Diagnostic Ultrasound System

Apr 6, 2016
13 days to decision

K160807 · Product code: **IYN** · Radiology
Source: https://www.510kdatabase.net/k160807/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Mar 24, 2016
Decision date	Apr 6, 2016
Days to decision	13 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

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