FDA 510(k) Premarket Notification

K093563 IU22 ULTRASOUND SYSTEM AND TRANSDUCERS

CLEARED

Feb 1, 2010
75 days to decision

K093563 · Product code: **IYN** · Radiology
Source: https://www.510kdatabase.net/k093563/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Nov 18, 2009
Decision date	Feb 1, 2010
Days to decision	75 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

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