

K113613 DIGITAL COLOR DOPPLER ULTRASOUND IMAGING SYSTEMJun 15, 2012
192 days to decisionK113613 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k113613/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Dec 6, 2011
Decision date	Jun 15, 2012
Days to decision	192 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Shantou Institute of Ultrasonic Instruments
Location	Walnut Creek, CA, US
Contact	FLOWER CAI
510(k) history	11 submissions · 11 cleared · 1997-2012

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k113613/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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