

K110841 DIGITAL COLOR DOPPLER ULTRASOUND IMAGING SYSTEM, CONVEX / LINEAR / PHASED ARRAY TRANSDUCERApr 15, 2011
21 days to decisionK110841 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k110841/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Mar 25, 2011
Decision date	Apr 15, 2011
Days to decision	21 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Shantou Institute of Ultrasonic Instruments (Siui
Location	Dublin, CA, US
Contact	FLOWER CAI
510(k) history	5 submissions · 5 cleared · 2006-2011

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k110841/> 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 17, 2026