

K131088 PORTABLE DIGITAL COLOR DOPPLER ULTRASOUND SYSTEMMay 24, 2013
36 days to decisionK131088 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k131088/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Apr 18, 2013
Decision date	May 24, 2013
Days to decision	36 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sonoscape Company Limited
Location	Dublin, CA, US
Contact	TOKI WU
510(k) history	22 submissions · 22 cleared · 2004-2015

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k131088/> 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 16, 2026