

**K130801 DIGITAL COLOR DOPPLER ULTRASOUND SYSTEM**Jun 14, 2013  
84 days to decisionK130801 · Product code: **IYN** · Radiology  
Source: <https://www.510kdatabase.net/k130801/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Mar 22, 2013
Decision date	Jun 14, 2013
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k130801/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 16, 2026