

K142815 S22 Digital Color Doppler Ultrasound System

Jan 28, 2015
121 days to decision

K142815 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k142815/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Sep 29, 2014
Decision date	Jan 28, 2015
Days to decision	121 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

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Device record: <https://www.510kdatabase.net/k142815/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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