

**K160258 X5 Digital Color Doppler Ultrasound System**Apr 1, 2016  
60 days to decisionK160258 · Product code: **IYN** · Radiology  
Source: <https://www.510kdatabase.net/k160258/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Feb 1, 2016
Decision date	Apr 1, 2016
Days to decision	60 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sonoscape Medical Corp.</b>
Location	Shenzhen, CN
Contact	Toki Wu
510(k) history	24 submissions · 24 cleared · 2015-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k160258/> 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 June 3, 2026