

**K163427 X3 Exp/X3/X3 Pro/X1 Pro/X1 Digital Color Doppler
Ultrasound System**

Jan 3, 2017
28 days to decision

K163427 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k163427/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Dec 6, 2016
Decision date	Jan 3, 2017
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k163427/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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