

K182648 X5 Series Digital Color Doppler Ultrasound SystemJan 29, 2019
127 days to decisionK182648 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k182648/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Sep 24, 2018
Decision date	Jan 29, 2019
Days to decision	127 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

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