

**K160853 Apogee 5500/Apogee 5300/ Apogee 5800 Digital Color Doppler Ultrasound Imaging System**Jun 27, 2016  
91 days to decisionK160853 · Product code: IYN · Radiology  
Source: <https://www.510kdatabase.net/k160853/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Mar 28, 2016
Decision date	Jun 27, 2016
Days to decision	91 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Shantou Institute of Ultrasonic Instruments Co., Ltd. (Siui)</b>
Location	Shantou, CN
Contact	Flower Cai
510(k) history	8 submissions · 8 cleared · 2016-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k160853/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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