

**K210317 Apogee 1000/ Apogee 1000Neo/ Apogee 1000Lite/
Apogee 1000Exp/ Apogee 1000B/W / Apogee 1U/ Apogee 1T/
Apogee 1G Digital Color Doppler Ultrasound Imaging System**Aug 19, 2021
197 days to decisionK210317 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k210317/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Feb 3, 2021
Decision date	Aug 19, 2021
Days to decision	197 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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