

**K202353 SR-2300 Portable DR Imaging System, SR-2300S
Portable DR Imaging System**

Dec 23, 2020
127 days to decision

K202353 · Product code: IZL · Radiology
Source: <https://www.510kdatabase.net/k202353/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Mobile (IZL)
Date received	Aug 18, 2020
Decision date	Dec 23, 2020
Days to decision	127 days
Third-party review	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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k202353/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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