

K200637 SR-8100 Portable X-ray UnitJul 9, 2020
121 days to decisionK200637 · Product code: **IZL** · Radiology
Source: <https://www.510kdatabase.net/k200637/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Mobile (IZL)
Date received	Mar 10, 2020
Decision date	Jul 9, 2020
Days to decision	121 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

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