

K253058 Portable DR Imaging SystemJun 18, 2026
269 days to decisionK253058 · Product code: **IZL** · Radiology
Source: <https://www.510kdatabase.net/k253058/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Mobile (IZL)
Date received	Sep 22, 2025
Decision date	Jun 18, 2026
Days to decision	269 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Shantou Institute of Ultrasonic Instruments Co., Ltd.
Location	Shantou, CN
Contact	Zeqin Chen
510(k) history	3 submissions · 3 cleared · 2024-2026

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