

K242515 uDR 380i ProOct 10, 2024
48 days to decisionK242515 · Product code: **IZL** · Radiology
Source: <https://www.510kdatabase.net/k242515/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Mobile (IZL)
Date received	Aug 23, 2024
Decision date	Oct 10, 2024
Days to decision	48 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shanghai United Imaging Healthcare Co., Ltd.
Location	Shanghai, CN
Contact	Xin Gao
Website	https://www.united-imaging.com
510(k) history	82 submissions · 82 cleared · 2018-2026

Shanghai United Imaging Healthcare Co., Ltd. is a medical imaging company based in Shanghai, China. The company develops and manufactures advanced diagnostic imaging systems and related technologies. The company has received FDA 510(k) clearances from total submissions, with all submissions focused on Radiology devices. FDA 510(k) clearances span from 2018 to 2026, demonstrating sustained regulatory activity and recent market approvals. Recent cleared devices include advanced imaging systems such as magnetic resonance imaging (MRI) platforms, computed tomography (CT) scan...

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Device record: <https://www.510kdatabase.net/k242515/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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