

**K243397 uMR 680**Jul 16, 2025  
258 days to decisionK243397 · Product code: **LNH** · Radiology  
Source: <https://www.510kdatabase.net/k243397/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Oct 31, 2024
Decision date	Jul 16, 2025
Days to decision	258 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Shanghai United Imaging Healthcare Co., Ltd.</b>
Location	Shanghai, CN
Contact	Gao Xin
Website	<a href="https://www.united-imaging.com">https://www.united-imaging.com</a>
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...