

**K183014 uPMR 790**Feb 27, 2019  
119 days to decisionK183014 · Product code: **OUO** · Radiology  
Source: <https://www.510kdatabase.net/k183014/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tomographic Imager Combining Emission Computed Tomography With Nuclear Magnetic Resonance (OUO)
Date received	Oct 31, 2018
Decision date	Feb 27, 2019
Days to decision	119 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Shanghai United Imaging Healthcare Co., Ltd.</b>
Location	Shanghai, CN
Contact	Shumei Wang
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...

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