

**K210418 HYPER Focus**Apr 9, 2021  
57 days to decisionK210418 · Product code: **KPS** · Radiology  
Source: <https://www.510kdatabase.net/k210418/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Tomography, Computed, Emission (KPS)
Date received	Feb 11, 2021
Decision date	Apr 9, 2021
Days to decision	57 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	Xin Gao
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...