

K183164 uWS-MRMar 22, 2019
127 days to decisionK183164 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k183164/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Nov 15, 2018
Decision date	Mar 22, 2019
Days to decision	127 days
Third-party review	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...
